ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND

by

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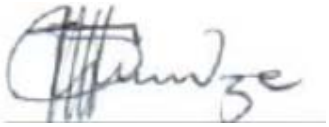
DECLARATION

I declare that **ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND** is my own work and that all sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.



15 November 2018

SIGNATURE **DATE**

Bhekisisa Senzo Tsabedze

ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND

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ABSTRACT

Background: In 2015**,** Swaziland had a tuberculosis (TB) prevalence of 733 per 100 000 population and HIV prevalence of 27.5%. Baylor College of Medicine Children's Foundation Swaziland (BCMCFSD) reported 83% prevalence of malnutrition amongst children in 2014. No study has described the association between malnutrition and childhood TB in Swaziland.

Purpose: To examine the association between malnutrition and diagnosed drug susceptible tuberculosis (TB) amongst children aged zero to fifteen years old in Swaziland.

Method: The Mixed Method approach was used to conduct the study. A total of 306 children's electronic records were extracted, then 12 children's caregivers interviewed. Extracted data were cleaned and exported to an excel database, then analysed using STATA version 14 by a statistician. Qualitative data were analysed using NVIVO version 11 post the analysis of the quantitative data. Triangulation of quantitative and qualitative results was conducted to obtain a comprehensive picture of the study. Validity, reliability, trustworthiness and adherence to ethical considerations were maintained.

Results: History of previous TB treatment, HIV status and age were strongly associated with poor TB outcome (<0.001) and severe malnutrition (<0.002). Sex, regions and TB type were statistically insignificant. Nutritional situation at home and nutritional support from the health care facility, emerged as themes.

Conclusion: TB and Malnutrition are significant predictors of children mortality, thus the children caregivers need consistent health education and support.

KEY CONCEPTS

Caregiver, Children, Drug, Malnutrition, Susceptible, Tuberculosis

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Dedication

To God, my parents and everyone that has contributed in my academic growth from lowest grade to date, I would love to forward my sincere gratitude. Myeni and Simelane families taught me that education will parent me, without it our lives will stumble. They always encouraged me to be courageous and be consistent in hope as there is always a light at the end of a tunnel. Thank You!

I also dedicate this to my loving wife, Mrs. Phiwayinkosi Nompumelelo Tsabedze and our children Agape and Asante for their love, support and understanding. May the Almighty God Bless you all.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immuno-deficiency Syndrome
ART	Anti-Retroviral Syndrome
ATT	Anti-TB Therapy
BCMCF-SD	Baylor College of Medicine Children's foundation- Swaziland
CDC	Centres for Disease Control and Prevention
CRX	Chest X-Ray
DHS	Demographic Health Survey
DST	Drug Susceptible TB
EBF	Exclusive Breast Feeding
EMR	Electronic Medical Record
FAO	Food and Agricultural Organisation
GHI	Global Hunger Index
GXP	GeneXpert
HB	Haemoglobin
HIV	Human Immuno-deficiency Virus
IRB	Institutional Research Board
LTBI	Latent TB Infection
M&E	Monitoring & Evaluation
MICS	Multiple indicator cluster survey
MoH	Ministry of Health
MUAC	Middle Upper Arm Circumference
NDMA	National Disaster Management Agency
NTCP	National TB Control Program
PEM	Protein Energy Malnutrition
RHZE	Rifampicin, Isoniazid, Pyrazinamide and Ethambutol
SEC	Scientific & Ethics Committee
SIgA:	Secretory immunoglobilin A
SOPH:	School of Public Health
TB	Tuberculosis
UNICEF	United Nations International Children's Emergency Fund
UNISA	University of South Africa
V/L	Viral load
GHI	Global Hunger Index
WHO	World Health Organisation

CHAPTER 1
ORIENTATION TO THE STUDY

1.1 INTRODUCTION

The association between malnutrition and tuberculosis (TB), is that TB worsens malnutrition and malnutrition weakens the immunity, thereby increasing the likelihood that latent TB develops into active disease. (Mohamed-Hussein, Salama, Khalil & Eid 2016:58-59 and Jaganath & Mupere 2012:1808-1809). TB is one of the public health threats and results in worse outcomes when combined with malnutrition. Children are mostly affected by these two diseases (malnutrition and tuberculosis). In 2013, malnutrition was the underlying cause of death for at least 3.1 million children around the globe (WHO 2015:1 and Jaganath & Mupere 2012:1808).

Malnourished individuals have increased susceptibility to diseases, since malnutrition hinders cell-mediated immunity, thus increases vulnerability of the affected individuals to infectious diseases such as TB and Human Immunodeficiency Virus (HIV). TB is among the four leading causes of child mortality around the globe. The World Health Organization (WHO) reported that TB was linked to 45% of all childhood deaths in 2013. Most of the affected countries are in the developing world including Swaziland (WHO 2015:1-2).

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

Global information and advice on HIV and Acquired immune deficiency syndrome (AIDS) (2015:16) state that Swaziland, a developing country in Southern Africa, has a high incidence of both HIV and TB. Swaziland has currently a high prevalence of HIV infection at 27.5% for the ages of 15 to 49 years old and is the third highest incidence of TB disease at 733 per 100 000 population (Mchunu, van Griensven, Hinderaker, Kizito, Sikhondze, Manzi, Dlamini & Harries 2016:105).

However, since the researcher started nursing practice at Baylor College of Medicine Children's Foundation (BCMCF-SD), the number of malnourished children with TB has increased constantly. The annual report for BCMCF-SD revealed that the prevalence of malnutrition amongst children and adolescents less than 19 years old was at 83% (BCMCF- SD 2015:15).

Moreover, no study has described the spectrum of malnutrition in TB diseased children in Swaziland, nor has there been a study that has explored the association between malnutrition and TB diagnosis amongst children between the ages zero nor 15 years at BCMCF-SD. Therefore, the researcher recognized the significance to examine the association between malnutrition and the diagnosis of drug susceptible TB amongst children aged zero to 15 years old and explore the perceptions of the children's caregivers with regard to paediatric nutrition during TB treatment.

1.2.1 The source of the research problem

Despite the burden of both malnutrition and TB in children worldwide, there are few studies on the mechanisms that underlie this relationship. But research indicated that malnutrition is a predictor of TB disease and was associated with worse TB outcomes and poor TB outcomes (Jaganath & Mupere 2012:1809).

WHO (2015:8-9), further explains that the association between TB and malnutrition is that TB has made malnutrition worse, which weakens immunity, thereby increasing the likelihood of developing TB. Yet, most individuals with TB disease are in a catabolic state and experience weight loss and some show signs of vitamin and mineral deficiencies at diagnosis.

1.2.2 Background to the research problem

The problem of the study emanates from the experience of the researcher as a clinician. During the researcher's time of working in a paediatric TB/HIV clinical setting at BCMCF-SD, the researcher noticed that most of the children who started TB treatment were severely malnourished and seemed to have poor TB outcomes. However, the malnutrition

was not directly responsible for the worst TB outcomes in the clinical setting. Some children who were considered mild, moderate and severely malnourished did not spontaneously have the worst TB outcomes after nutrition assessment. A nutritional assessment plan was developed to rule out nutritional status as the sole cause of poor TB outcomes.

1.3 RESEARCH PROBLEM

Even though, the nurses and doctors at BCMCF-SD implement quality client care as per the national TB, HIV and Malnutrition Guidelines to all TB clients seen at the facility, there has been a constant increase in the number of deaths while on TB treatment. The TB register at BCMCF-SD indicates that in 2015 out of 40 children diagnosed with both malnutrition and TB, seven of them died. However, in 2014 a total of 37 children were diagnosed with TB and malnutrition, with case fatality of four. The number of children that fell under the other poor TB outcomes in 2015 was five and these included treatment failure, lost to follow up, TB relapse and not evaluated. During the care most of the children were supplied with plumpy nut and food by prescription by their caregivers, but malnutrition at times persisted. Some few caregivers confessed that they used these food packages and the plumpy nut for the sick to feed the entire family.

Although, some literature suggests that poor nutrition is associated with poor TB outcomes, the need to examine the association between the nutritional status and TB outcomes still remained a priority (WHO 2015:7). The study intended to help, guide and improve the quality of care to all malnourished TB and TB/HIV co-infected clients, especially children aged zero to 15 years old, who were most commonly affected by malnutrition in Swaziland.

1.4 AIM OF THE STUDY

1.4.1 Research purpose

The purpose of the study was to examine the association between malnutrition and diagnosed drug susceptible TB amongst children aged zero to 15 years old.

1.4.2 Research objectives

A research objective is a concrete, measurable end towards which effort or ambition is directed (Dlamini 2016:27). The objectives of the study were divided into objectives for phase one and the objective for phase two of the study. The objectives were to:

1.4.2.1 Objectives for phase one

- Describe the clinical and demographic characteristics of malnutrition amongst children less than 15 years of age with drug susceptible tuberculosis.

- Examine the factors associated with malnutrition and drug susceptible tuberculosis diagnosis amongst children less than 15 years of age.

1.4.2.2 Objective for phase two

- Explore and describe the perceptions of the children's caregivers with regard to paediatric nutrition during TB treatment.

1.4.3 RESEARCH QUESTIONS

The research questions were based on the objectives of the study and were as follows:

1.4.3.1 Research questions for phase one

- What are the clinical and demographic characteristics amongst malnourished children less than 15 years of age diagnosed with drug susceptible tuberculosis?

- What are the factors associated with malnutrition and drug susceptible tuberculosis diagnosis amongst children less than 15 years of age?

1.4.3.2 Research question for Phase two

- What are the perceptions of the children's caregivers with regard to paediatric nutrition during TB treatment?

1.5 SIGNIFICANCE OF THE STUDY

The results of the study are intended to help in determining the association between malnutrition and TB disease outcomes in children less than 15 years of age. It has provided an evidence base for more comprehensive integration between nutrition programs, TB treatment programs and HIV programs. Furthermore, the results of the study have contributed to the growing body of knowledge about the association between malnutrition and diagnosed drug susceptible TB among children aged zero to 15 years old. The findings of the study are aimed at informing the policy makers to formulate appropriate policies and guidelines that would address the issues of malnutrition on TB and TB/HIV co-infection. The guidelines and policies would guide and improve the quality of care to all TB clients, especially children aged between zero and 15 years.

1.6 DEFINITIONS OF TERMS

1.6.1 Caregiver: refers to anyone who provides assistance to someone else who is, in some degree, incapacitated and needs help (Barrett & Blackburn 2010:3). In the study, the term caregiver is defined as an individual between the ages of 18 years to 65 years old, who was responsible for caring a child diagnosed with drug susceptible TB during the study period.

1.6.2 Children: refer to human beings that are below the age of eighteen (Mason-White & Kearney 2012:1). However, in the study, the term children refers to individuals aged from zero to 15 years old treated for drug susceptible TB at BCMCF-SD from 01 January 2008 to 31 July 2016.

***1.6.3 Drug susceptible TB*:** refers to non-resistant TB strain that can be effectively treated will any TB drugs as long as the Tb drugs are properly taken (Nahid, Dorman, Alipanah, Barry, Brozek, Cattamanchi, Chaisson, L. Chaisson, Daley, Grzemska & Higashi. 2016:150). In the context of this study, drug susceptible TB refers to all the electronic medical records that had a mycobacterium TB not detected results and those that had a mycobacterium TB detected drug susceptible to all the first line TB drugs.

1.6.4 Malnutrition*:* refers to any physiological condition caused by deficiencies, excess or imbalances in energy or nutrients necessary for a healthy and active life. It encompasses over-nutrition, undernutrition and micronutrient deficiencies (d' Errico & Pietrelli 2017:5) Therefore, in the context of this study malnutrition refers to underweight, stunting and wasting of children from zero to 15 years old without considering overweight, as measured by Z-Scores.

1. 6.5 Tuberculosis: refers to bacterial infection spread through inhaling tiny droplets from the coughs or sneezes of a person infected with the TB bacilli. It mainly affects the lungs, but it can affect any part of the body, including the abdomen, glands, bones and nervous system (Otu, Hashmi, Mukhtar, Kwizera, Tiberi, Macrae, Zumla, Dünser & Mer 2018:10). In the context of this study, TB refers to a clinical diagnosis made by a qualified Nurse or Doctor to a child aged zero to 15 years old through bacteriological confirmation, chest X-ray or clinical presentations.

1.7 RESEARCH DESIGN AND METHODS

The mixed method approach used in the study was explained in detail in Chapters three and four. Phase one of the study was the quantitative phase and it was explained in Chapter 3. Phase two of the study was the qualitative phase and it was explained in Chapter 4. The researcher conducted phase one of the study and after its analysis, the results were used to purposefully select caregivers that met the inclusion criteria.

1.8 SCOPE AND LIMITATIONS

Phase one of the study was limited to Electronic Medical Records (EMRs) of children aged zero to 15 years old that were treated for TB disease at BCMCF-SD in Mbabane from the 1st January 2008 to 31st July 2016. Phase two of the study enrolled a total of 12 caregivers of the children less than 15 years old, whose EMRs were selected for data extraction.

1.9 ETHICAL CONSIDERATION

The ethical principles of autonomy, beneficence and non-maleficence were observed throughout the study. Ethical clearance was sought and obtained from UNISA Research Ethics Committee Department of Health Studies, University of South Africa (UNISA), BCMCF-SD internal research board (IRB), Basic Research Assurance International Network (BRAIN) and the Swaziland Scientific and Ethics Committee (SSEC). Permission to conduct the study was sought from BCMCF-SD Executive Director. After permission was granted the researcher got the EMRs that were eligible for phase one of the study through assistance from the BCMCF-SD's monitoring and evaluations (M&E) officer.

After the analysis of phase one of the study, the researcher purposively identified caregivers of the children whose EMRs were selected for extraction that met the eligibility criteria for phase two of the study. An explanation was given to the participants about the purpose of the study and their expectations. The goals of the study were stated and how the data would be used. The participants were told about the type of data to be collected and the procedure to be followed. The estimated time for the interview was also stated.

The participants were told that the study was for academic purposes and therefore, there would be no incentives for participation. The researcher explained to the participant, how they were selected from the eligible population. They were assured that there would be no physical risk in the study; but that emotions may be triggered and that there might be psychological trauma, which would be cared for by a dedicated social worker or psychologist. The participants were assured that confidentiality would be maintained with all data and complete anonymity was guaranteed. Their privacy was respected throughout. It was explained that participation was strictly voluntary and that they had the right to withdraw from the study anytime or to refuse to provide any specific information. The participants were provided with information of the researcher and BCMCF-SD to contact should they have any questions or comments regarding the study.

1.10 VALIDITY AND RELIABILITY

1.10.1 Validity

Validity refers to the degree of accuracy to which an instrument measures what it is supposed to measure in-order to obtain accurate and truthful study results (Polit & Beck 2012:768). The five types of validity were observed by the researcher throughout the study; external, internal, content, face and construct validity. The study was externally valid since the researcher obtained a sample that was representative of the broader population (Polit & Beck 2012:216).

Internal validity was observed through the support of the co-supervisor of this study. The co-supervisor also assisted the researcher in using appropriate statistical software to ensure internal validity (Nxumalo 2011:77).

The research supervisor and the co-supervisor assisted the researcher in making sure that the content of this study is valid. A panel of experts at BCMCF-SD have evaluated and documented the content validity of the study instruments. They also made sure that the study instruments were relevant to the study.

Polit and Beck (2012:718) define face validity as the extent to which a research instrument looks as though it is measuring what it supposed to measure. The measurement of face validity of the tool was done by giving it to the supervisor for acceptance and to a professional statistician to establish whether the tool was sufficiently comprehensive in seeking the proper range of responses.

According to Polit and Beck (2012:750), construct validity refers to the inferences from observed persons, settings and interventions in a study to the constructs that these instances might represent with an instrument and the degree to which an instrument measures the construct under investigation. Construct validity was applied through conducting literature review on childhood TB and malnutrition in order to ensure that all the different aspects were covered in the questionnaire (Nxumalo 2011:77).

1.10.2 Reliability

According to Joubert and Ehrlich (2013:117), reliability means the degree of consistency or accuracy with which an instrument measures the attribute it is designed to measure. Reliability of the tool in the study was ensured by accurate and careful phrasing of each question to avoid ambiguity and to lead respondents to a specific answer. Respondents were informed of the purpose of the interview and the need to respond truthfully. In addition, a pre-test of the data collecting tool was conducted to identify any problems and data cleaning was conducted.

1.11 MEASURES TO ENSURE TRUSTWORTHINESS

Trustworthiness is the degree of confidence qualitative researchers have in their data and is assessed using the criteria of: credibility, dependability, confirmability and transferability and authenticity (Polit & Beck 2014:394). The five criteria were adopted in ensuring trustworthiness in the study and were discussed further in chapter 3.

1.12 STRUCTURE OF THE DISSERTATION

The structure of the dissertation is presented as follows:
Chapter 1: Orientation to the study
Chapter 2: Literature review
Chapter 3: Research design, methods and results for phase one
Chapter 4: Research design, methods and results for phase two
Chapter 5: Summaries, integration of results and conclusions

1.13 CONCLUSION

In this chapter, the introduction and background of the research problem were explained. The statement of the research problem, purpose, objectives and research questions were stated. The significance of the study was explained and key concepts defined. The process-oriented framework for the association between malnutrition and diagnosed drug susceptible TB amongst children less than 15 years old will be discussed in details from Chapter 2 to Chapter 5 of the study.

Ethical considerations, which were followed in this study were introduced. The criteria for validity, reliability and trustworthiness of the study were also introduced. The next chapter focuses on the literature review.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Literature review is a process whereby a researcher integrates different views of writers, criticizes previous scholarly works, synchronises related topics and identifies the related issues that are significant in the field of study (Creswell 2014:25). It is the section of a research study that searches what other researchers have established about the research problem from scanning literature; what other scholars have written about the proposed research topic and also identifies the theories that address the topic. It enables the researcher to show how the research findings by other scholars add to the already existing body of knowledge (Babbie 2013:499).

The chapter reviewed literature related to the study topic. The key phrases that were used to search literature were association, children, diagnosis, drug, malnutrition, susceptible and tuberculosis. The researcher consulted with the Department of Health Studies librarian at the University of South Africa (Unisa) to help with search of studies that met the eligibility criteria. Only studies that were conducted from 2010 to 2017 were selected for literature review.

Therefore, in this study, the researcher has reviewed different studies, reports and other publications relevant to the association between malnutrition and diagnosed with drug susceptible tuberculosis amongst children aged zero to fifteen years old. This chapter describes in detail children's malnutrition, diagnosis of drug susceptible TB and the association between malnutrition and diagnosed drug susceptible TB amongst children aged zero to fifteen years of age.

2.2 MALNUTRITION

Engelbert, Bain, Awah, Geraldine, Kindong, Sigal, Bernard, Tanjeko (2013:88) report that malnutrition contributes about one third of all children deaths worldwide, whereas child malnutrition is associated with 54% of deaths amongst children in the developing countries. Poverty remains the major contributing factor to the high mortality rates. The

vicious cycle of poverty, disease and illness worsens this situation. Rosenberg, Wachter and Weintraub (2015:2) further report that malnutrition is among the four leading causes of child mortality around the globe. The World Health Organisation (WHO) (2014:122) reported that in 2013, malnutrition was rated at 45% mortality rates amongst children and contributed to 60.7% deaths of children diagnosed with diarrhoeal diseases, 57.3% of deaths associated with malaria, 52.3% deaths associated with pneumonia and 44.8% of deaths from measles. The report also estimated that about 26.5% of children in developing countries were stunted in 2005.

Literature also reports that about nine million children are severely wasted in developing countries and malnutrition is accountable for 11% of the total global disease burden and 35% of child deaths worldwide. The sub-Saharan Africa has a high incidence of HIV infection and that causes an added challenge to the care of malnourished children. Even though clinical interventions for many common causes of childhood mortality worldwide have been managed over the last decade, the management of severe wasting disease and malnutrition in children particularly in those infected with HIV and/or TB remains poorly addressed (Trehan, O'hare, Phiri & Heikens 2012:1).

Food and Agriculture Organization (FAO) of the United Nations (2013:1) states that 14% of the population in developing countries were undernourished in the period between 2011 and 2013. The malnourished individuals suffer physical malfunctions to the point where the individuals can no longer maintain adequate bodily performance processes, such as growth, pregnancy, lactation, physical work and resistance to and recovering from diseases (Vira, Agarwal, Jamnadass, Kleinschmit, McMullin, Mansourian, Neufeldt, Parrotta, Sunderland, & Wildburger 2015:4). Thus, malnutrition results in disability, morbidity and mortality, especially among infants and young children under five years of age. Malnutrition often begins in utero and child malnutrition is closely linked to poverty, low levels of education and poor access to health services, including reproductive health and family planning. Under-nutrition is mostly associated with developing countries like Nigeria (Demographic Health Survey (DHS) of Nigeria 2013:175).

Maseko-Masuku and Owaga (2012:5995) state that malnutrition is a major confounding factor for child morbidity and mortality in developing countries. The Swaziland Multiple Indicator Cluster Survey (MICS) (2014:3) indicated that 25.5% of the children less than five years old were moderately stunted and 7.2% the same age group were severely

stunted in growth. Moderate and severe underweight remains at 5.6% and 1.6% respectively, whereas wasting remains at 2.4%.

When disaggregating the prevalence of malnutrition according to regions the Hhohho Region has the highest prevalence of underweight children 8.2% relative to other regions such as Shiselweni 7.3%, Lubombo 6.7% and Manzini 6.4%. However, Lubombo Region has the highest cases of under-five mortality rate (deaths per 1,000 live births) of 115 when compared to rates in other regions; Manzini 112, Shiselweni 100 and Hhohho 96 (Maseko-Masuku & Owaga 2012:5995).

A study conducted at the national referral hospital, Mbabane Government situated in the Hhohho region indicated that case fatality rates for childhood malnutrition remain very high in Swaziland, irrespective of the implementation of the WHO treatment guidelines. The case fatality rate for childhood malnutrition was reported to be at 40.1% and the WHO considers rates above 20% unacceptable. Even the rate for moderate malnutrition was very high at 27.5% (Benyera & Hyera 2013:134). The annual report of BCMCF-SD for the year 2014/15 reports that the prevalence of malnutrition amongst children and adolescents at BCMCF-SD was at 83% in 2015. There is no subgroup data to describe the nutritional status for the different age categories (BCMCF-SD Report 2015:16).

Benyera and Hyera (2013:127) further report that the severity of malnutrition and the presence of co-morbid conditions have an additional mortality risk among malnourished children at Mbabane government hospital. The mortality for severe malnutrition was found to be at 46.9% compared with 27.6% for moderate malnutrition. Malnourished children with co-morbid like pneumonia and those with gastro-enteritis were about twice as likely to lose their lives as those without.

2.2.1 The causes of malnutrition

Masuku-Maseko and Owaga (2014:5995) state that the potential determinants of childhood malnutrition and mortality in Swaziland can be categorized into three levels, that include immediate causes (inadequate dietary intake of protein, energy and micronutrients); diseases such as pneumonia, diarrhoeal diseases and HIV/AIDS); underlying causes (inadequate access to food due to poverty and decline in food production); inadequate care of children and women, insufficient health services and

unhealthy environment) and basic causes (inadequate mother's education and nutrition knowledge, insufficient human resources in child health care; inadequate policies on child nutrition and health care; inequitable distribution of household and national socioeconomic resources). The causes of malnutrition are summarised by the conceptual framework in figure 2.1 below:

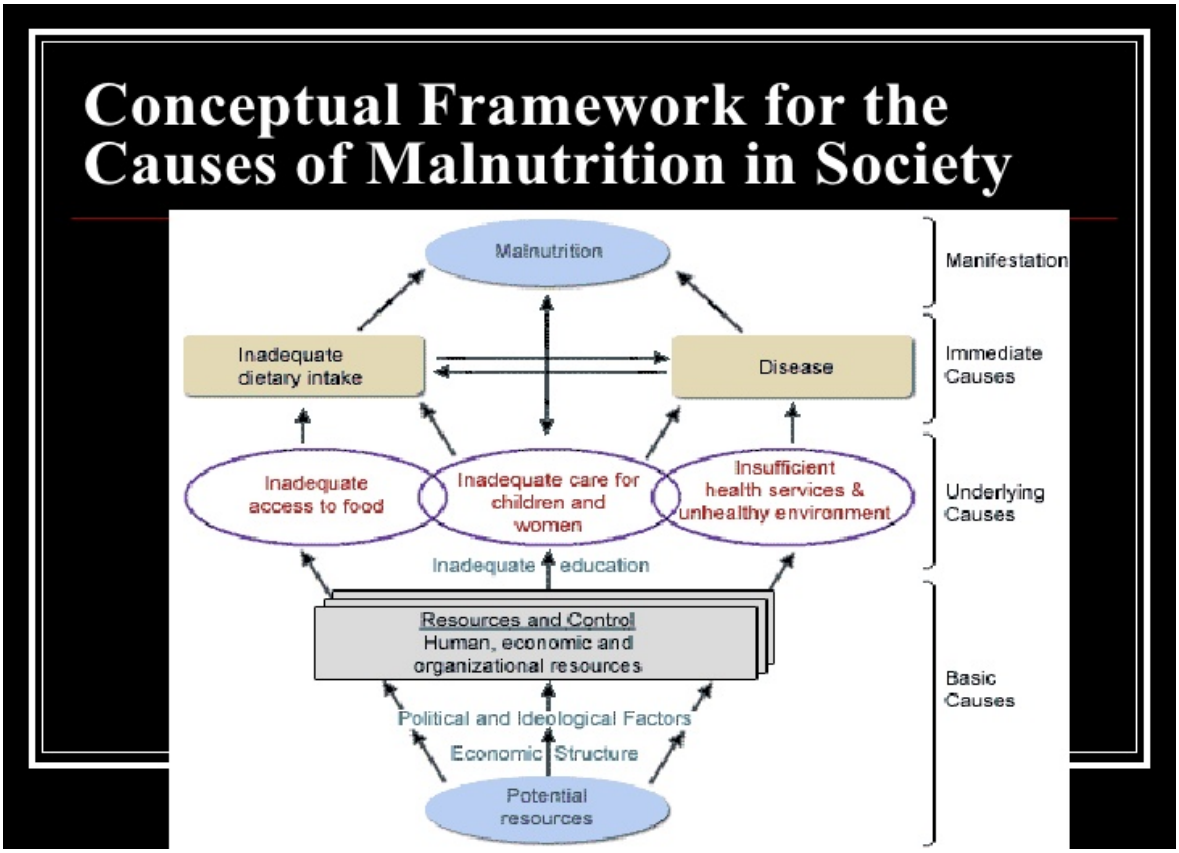

Figure 2.1. Conceptual Framework for malnutrition in Society (UNICEF, 2015)

According to Rosenberg, Wachter, Campbell, Rhatigan and Weintraub (2015:3), food insecurity is a cause of malnutrition and this insecurity usually appears as a result of an individual being predisposed to a number of factors that include poor agricultural production of food; the preservation of food, the population explosion, the prevalence of poverty; political ideologies; and disease and infection epidemiology. The causes can be categorized under clinical, social and environmental factors.

Clinical causes arise as a result of infections and health problems such as cancer, diarrhoeal diseases and HIV which limit the body's ability to absorb sufficient nutrients and calories, thus predisposing an individual to malnutrition. Secondly, the low social

status can lead to household food insecurity, making family members more vulnerable to infection or other clinical causes of malnutrition. The environmental factors can become a source of malnutrition, for instance rural areas tend to be more affected than urban areas. Food security in rural communities depends on natural and human resources that are vulnerable to change, including rain or weather patterns, access to tools, agricultural knowledge and human capital (Rosenberg et al. 2015:3).

2.2.2 Breastfeeding

Kramer and Kakuma (2012:14) indicated that exclusive breastfeeding (EBF) is another important aspect of child nutrition in the first six months of life, since it provides the child with all the required nutrients and it reduces the risk of infant mortality and morbidity. The MICS (2014:4) indicates that the uptake of EBF remains low in Swaziland at it stands at 63.8 and age appropriated feeding for under-fives remains at 45.3%.

Kuku-Shittu, Onabanjo, Fadare and Oyeyemi (2016:16) state that breastfeeding practices and institution of complementary foods are important determinants of the nutritional status of children, mainly those under the age of two years. The prevalence of a low level of breastfeeding for children under five years old is highest among rural small-scale farmer households because many lactating women are undernourished to provide adequate milk for their baby; as a result they tend to supplement breast milk with cereal food products.

2.2.3 MEASUREMENTS FOR MALNUTRITION IN CHILDREN

The Swaziland Severe Acute Malnutrition Management guidelines (2015:4) categorizes nutrition anthropometric measurements and nutrition status as shown in the tables 2.1A to 2.1C below.

Table 2.1A below is showing the classification of malnutrition measurements for wasting categorized by age groups adapted from The Swaziland Severe Acute Malnutrition Guidelines (2015:4).

Table 2.1A: Classification of malnutrition measurements for wasting		
Age Category	**Moderate Malnutrition**	**Severe Malnutrition**
0 to 6 months old	WHZ ≥-3 to ≤-2	WHZ ≤-3

7 to 59 months old	WHZ ≥-3 to ≤-2	WHZ ≤-3
	MUAC	MUAC < 11.5
5 to 10 years old	BMI for age: ≥-3 to <-2	BMI for age < -
	MUAC:≥13.5cm to< 14.5 cm	MUAC < 13.5cm
10 to 15 years old	BMI for age: ≥-3 to <-2	BMI for age < -
	MUAC: **≥** 16 cm < 18.5 cm	MUAC: < 16 cm

Table 2.1B below is showing the classification of malnutrition measurements for stunting categorized by age groups: adapted from The Swaziland Severe Acute Malnutrition Guidelines (2015:4).

Table 2.1B: Classification of malnutrition measurements for stunting		
Age Category	**Moderate Malnutrition**	**Severe Malnutrition**
0 to 6 months old	HAZ ≥-3 to ≤-2	HAZ ≤-3
7 to 59 months old	HAZ ≥-3 to ≤-2	HAZ ≤-3
5 to 10 years old	HAZ: ≥-3 to <-2	HAZ < -3
10 to 15 years old	HAZ: ≥-3 to <-2	HAZ < -3

Table 2.1C below is showing the classification of malnutrition for underweight categorized by age groups: adapted from The Swaziland Severe Acute Malnutrition Guidelines (2015:4).

Table 2.1C: Classification of malnutrition measurements for underweight		
Age Category	**Moderate Malnutrition**	**Severe Malnutrition**
0 to 6 months old	WAZ ≥-3 to ≤-2	WHZ ≤-3
7 to 59 months old	WAZ ≥-3 to ≤-2	WHZ ≤-3
5 to 10 years old	BMI for age: ≥-3 to <-2	BMI for age < -3
10 to 15 years old	BMI for age: ≥-3 to <-2	BMI for age < -3

2.2.4 MANAGEMENT OF MALNUTRITION IN CHILDREN

A multi-sectorial approach is vital in the effective management of malnutrition. This entails improvement in government policy. Fighting corruption and adopting a horizontal approach in implementing programs at community level must be recognized. Procuring

genetically modified foods to increase food production, and to survive adverse climatic conditions could be alternative gateways in solving these problems. Socio cultural peculiarities of each community are an essential baseline consideration for the implementation of any nutrition health promotion programs (Bain Awah, Geraldine, Kindong, Siga, Bernard & Tanjeko 2013:1).

2.3 Drug susceptible TB in children

Tuberculosis remains a significant cause of morbidity and mortality among children in resource-limited settings such as developing countries. Worldwide, there are nine million new tuberculosis infections every year, and 11% of them are in children. Malnutrition is also highly prevalent in children living in tuberculosis endemic countries like Swaziland and contributes to 2.2 million deaths in children under 5 years of age globally. Poverty, overcrowding, food insecurity and HIV further set the stage for both malnutrition and poor infection control (Janganath & Mupere 2012:1809).

2.3.1 Diagnosis of TB in children

TB disease occurs when an individual infected by Mycobacterium tuberculosis develops symptoms of TB disease and has test results that are consistent with TB disease: sputum that is positive by GeneXpert, smear microscopy or culture for TB organisms or a chest radiograph consistent with TB disease (Centre for Disease Prevention & Control (CDC) 2016:2). TB disease can also be diagnosed clinically, without micro-bacteriologic confirmation (WHO 2013:3). Bacteriologically confirmed TB case is one from whom a biological specimen is positive by smear microscopy, culture or GeneXpert. Clinically diagnosed TB case is one who does not fulfil the criteria for bacteriological confirmation, but has been diagnosed with active TB by a clinician based on clinical findings or through radiology and initiated on a full course of TB treatment (WHO 2013:3).

2.3.2 MANAGEMENT OF TUBERCULOSIS IN CHILDREN

According to the end TB strategy (2015:1), the declaration of tuberculosis as a global public health emergency in 1993 ended a period of prolonged global neglect of TB in children aged zero to fifteen years of old. The end TB strategy also advocate for directly observed treatment short course strategy (DOTS) and adoption of the prevention and control of TB during the sixty second World Health Assembly. The advocacy will help to

accelerate the global expansion of tuberculosis care and control. The Swaziland National TB Control Program (2013:56) insists that DOTS is a patient cantered approach and plays a key role in the prevention of treatment interruption, since the strategy entails that every TB client should have a treatment supporter throughout the course of the treatment.

The Swaziland National TB Control Program (NTCP) (2013:47) state that all TB case (new or previously treated) should have TB culture and Drug Sensitivity Test (DST) for the clinician to commence the client on appropriate regiment. The standard first line regimen for drug susceptible TB is Rifampicin (R), Isoniazid (H), Pyrazinamide (Z) and Ethambutol (E) for the first two months for new TB cases and three months for previously treated TB cases. The continuation phase of the TB management begins after the completion of the two or three months and lasts for a minimum of four months for new TB cases and five months for previously treated TB cases. In the continuation phase new TB cases are treated with RH and the previously treated TB cases with RHE. The treatment is administered per weight of the child and should be monitored monthly to adjust the doses.

2.3.3 EPIDEMIOLOGY OF TB IN SWAZILAND

According to the Swaziland country's TB profile report (2015:1), TB Prevalence is at 605/100 000 and the Incidence remains at 565/100 000 population. However, the Case detection is reported to be as low as 60%.Treatment success rate is at 78%, yet the target is 90% of treatment success rate as per the end TB strategy that the country adopted since 2015. This strategy envisions a world free of tuberculosis and zero deaths, disease and suffering due to tuberculosis (The end TB strategy 2015:4).

The WHO (2012:1) states that TB is one of the leading causes of morbidity and mortality among children aged zero to fifteen years old in Swaziland. The country had the highest estimated TB incidence rate of 565 TB cases per 100 000 population in 2013. An estimated 16 000 people developed active TB in 2011, and of these, around 47% were not notified. Around 77% of TB patients were co-infected with HIV in 2013. The TB mortality rate remained high at 53 per 100 000 (Swaziland TB Profile 2015:1).

2.3.4 TB outcomes

According to WHO (2013:2) TB outcomes can be classified into favourable and unfavourable outcomes. The favourable TB outcomes are those with desirable results and they consist of cured and treatment completed, whereas the unfavourable TB outcomes refers to those that result in undesirable results that include death, lost to follow up, died and not evaluated. Each of the TB outcomes is discussed in the table below.

Table 2.2: TB outcomes adapted from WHO (2013:5)

Outcome	Definition
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.
Treatment completed	A TB patient who completed treatment without evidence of failure, but with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable.
Treatment failed	A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.
Died	A TB patient who dies for any reason before starting or during the course of treatment.
Lost to follow-up	A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.
Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases transferred out to another treatment unit as well as cases with unknown treatment outcome by the reporting unit.
Treatment success	The sum of cured and treatment completed.

2.3.5 TB and other co-morbidities

The End TB Strategy (2015:14) reports that several non-communicable diseases and other health conditions including diabetes mellitus, under-nutrition, silicosis, as well as smoking, harmful alcohol and drug use and a range of immune-compromising disorders

and treatments are risk factors for tuberculosis. Kendall (2017:5-6) further reports that Pneumonia is a major cause of morbidity and mortality in infants and children less than 15 years old worldwide, with most cases occurring in tuberculosis-endemic settings. Acute severe pneumonia in children is regarded as a primary cause or underlying comorbidity for childhood TB. The presence of co-morbidities may complicate tuberculosis management and results in poor treatment outcomes. Conversely, tuberculosis may worsen or complicate management of other diseases. Therefore, as a part of basic and coordinated clinical management, people diagnosed with tuberculosis should be routinely assessed for relevant co-morbidities (The End TB Strategy 2015:14-16).

2.4 THE ASSOCIATION BETWEEN MALNUTRITION AND DRUG SUSCEPTIBLE TB

Hood (2013:1123) states that Protein Energy Malnutrition (PEM) and TB are the major public health concerns in developing countries like Swaziland. Malnutrition is an underlying cause of many deaths and when left untreated compromises the normal physical and cognitive development of children and adolescents. Moreover, TB continues to be serious infectious killer disease. Therefore, the PEM and TB have a synergistic relationship adversely having an impact on one another.

According to Jaganath and Mupere (2012:1809), there are limited studies conducted on the mechanisms that underlie this relationship. Malnutrition is a predictor of tuberculosis and is associated with worse TB outcomes. The worse TB outcomes occur because of malnutrition prohibiting cell mediated immunity in children, while increasing the risk of developing other respiratory infections like pneumonia. There is a critical need for research on childhood tuberculosis, specifically on how nutritional status affects the risk and progression of tuberculosis and whether nutritional supplementation improves clinical outcomes or prevents disease.

2.4.1 Impact of malnutrition on children diagnosed with TB

According to the End TB Strategy (2015:18), malnutrition is a significant determining factor of tuberculosis. Crowded and poorly ventilated living and working environments are often associated with poverty that constitutes a direct high risk for tuberculosis transmission. Under-nutrition increases the risk of developing an active TB disease from Latent TB Infection (LTBI). The poor population is usually ignorant about health

knowledge and have a lack of empowerment to act on the little health knowledge they have. As a result of the ignorance related to health issues, these poor populations find themselves in high risk of exposure to several tuberculosis risk factors.

In addition, Detjen, Gnanashanmugam and Talens (2013: 3) report that TB is often an unrecognized underlying disease in children with pneumonia, respiratory illness, HIV/ AIDS, or malnutrition and contributes to high child mortality and morbidity, even though it is preventable and curable. Childhood TB frequently remains undiagnosed because children with TB often are from poor families and live in overcrowded settings, with lack of knowledge about the disease and live in communities with limited access to health care. Even when the quality of care at health facilities is good, many caregivers may not be knowledgeable about these facilities, or they may be unwilling to seek care if the facility-based care is perceived as culturally inappropriate, inaccessible, or unaffordable.

Faddoul (2015:62) states that risk factors for TB infection in children less than fifteen years old include closeness to a TB case and duration of the contact with the TB case. Another risk factor is the smear positivity and presence of cavities on chest radiograph (CXR) of the TB source case. The first two years of life infer the greatest risk for developing active TB disease in addition to HIV infection, immunosuppression, malnutrition and other diseases. The disease mostly occurs within two years after exposure.

Malnutrition has been associated with increased risk of respiratory infections. Underweight increases the risk of an upper respiratory infection by 13% and wasting by 20% (Benyera & Hyera 2013:131). Janganath and Mupere (2012:206) add that Childhood Tuberculosis and Malnutrition are the significant predictors of mortality in children with pneumonia, attributing to 52.3% of pneumonia-related deaths.

2.5 CONCLUSION

This narrative review of recently published research and current knowledge may help explore and describe the association between malnutrition and TB in children less than 15 years old. The literature will assist the researcher to develop a well-informed discussion with regard to malnutrition and TB in children, which is one of the areas that lacks evidence-based guidance.

CHAPTER 3

RESEARCH DESIGN, METHODS AND RESULTS OF PHASE ONE

3.1 INTRODUCTION

In the previous chapters, the background and scope of the problem, literature on the association between malnutrition and diagnosed drug susceptible TB and objectives of the study to carry out the study have been addressed. Therefore, this chapter reports on the research design and methodology used to examine the association between malnutrition and diagnosed drug susceptible TB amongst children aged zero to fifteen years old in Swaziland. It outlined the steps taken when conducting phase one of the research. This included identification of an appropriate research design, study population, sample selection, data collection and analysis. It also highlighted the ethical considerations and measures to ensure reliability and validity. The findings of phase one of the study were also presented in this chapter.

3.2 RESEARCH DESIGN

The overall design is a multiple method. Creswell (2014:40) reports that multiple method has a pragmatism philosophical foundation that allow different worldviews and assumptions, as well as different forms of data collection and analysis to be included in one study. Therefore, the researcher used both the quantitative and the qualitative approaches collaboratively in the same study starting with a quantitative phase and followed by a qualitative phase. After conducting phase one of the study the researcher used the results for phase one to purposively select caregivers of the children who had malnourished children at the start of TB treatment but were able to achieve good TB outcomes versus those that had poor TB outcomes. Thus, the researcher conducted the quantitative analysis first then started the data collection and analysis for the later stage within two months. The researcher started with the quantitative approach first to examine the association between malnutrition and diagnosed drug susceptible TB before embarking on the qualitative phase of the study. After examining the association, the researcher designed the probes for the qualitative approach as guided by the result from the quantitative approach. Therefore, the main purpose for starting with quantitative approach was to efficiently maximize the researcher's understanding of the research

problem, so that when exploring and describing the perceptions of the children's caregivers the researcher could develop precise probes for phase two during data collection. The responses to probes in phase two enabled the researcher to have an explanation for the results in phase one.

The research design for the quantitative phase of the study is retrospective cohort design. Polit and Beck (2012:609) and Burns and Grove (2013:209), state that a retrospective cohort is a design, whereby the researcher uses historical data for a specific group in a current study. Easterby-Smith, Thorpe and Jackson (2012: 60) report that one advantage of this research design is that it increases the validity and generalisability of results and the potential theoretical contribution.

3.3 RESEARCH APPROACH

The approach of the study is a mixed method research, which combined both the quantitative and the qualitative approaches in one study (Terrell 2012:255). The researcher followed multiple method by starting with quantitative approarch and followed with qualitative approach. The two approaches occurred in two distinct interactive phases that were sequential. The quantitative approach was phase one and qualitative approach was phase two of the study (Wachira 2015:69-70). In phase one the researcher collected quantitative data and conducted the quantitative analysis then collected the qualitative data and conducted qualitative analysis at two different periods. Terrell (2012:272) further reports that the research design allows the researcher to collect and analyse quantitative data then followed by the collection and analysis of qualitative data. The two data sets were merged in chapter five of the study.

Phase one consisted of the retrospective, off-line extraction of data variables from aggregated database at BCMCF-SD's EMR system. The researcher extracted the EMRs with the following minimum variables: Demographic characteristic included the age, height, weight, middle upper arm circumference (MUAC) and clinical characteristics include GeneXpert (GXP) results, sputum smear results, sputum culture results, haemoglobin (HB), HIV status and CD4 Count. After data extraction from the EMRs of the children aged zero to fifteen years old diagnosed with drug susceptible TB, the data were cleaned and exported to an excel database. They were then sent to the statistician to be analysed using STATA version 14.

Mixed method approach was used to conduct the study and it is defined as a research approach in which the investigator collects and analyzes data, integrates the findings and draws inferences using both quantitative and qualitative approaches in a single study (Polit & Beck 2012:602). Burns and Grove (2013:208) reported that the mixed method approach recognises that all researchers bring assumptions to their studies. The assumptions may be from a point of view of the post-positivist (quantitative) or constructivist (qualitative). However, the philosophical underpinnings of this approach is pragmatism, which capitalises on both the representativeness and generalisability of quantitative research and the in-depth, contextual nature of qualitative research.

The researcher chose to use the mixed method approach because quantitative and qualitative approaches are complementary; they represent words and numbers, and these are the two fundamental languages of human communication. Thus, the researcher chose to address the research problem of the study with both approaches that can allow each to do what it does best and avoiding the limitations of a single approach (Polit & Beck 2012:604).

Secondly, the approach enabled the researcher to answer research questions that could not be answered by one approach (Polit & Beck 2012:604).

Moreover, the mixed method approach provided the researcher with an opportunity and encouragement for collaboration between quantitative and qualitative approaches working on the same problem (Polit & Beck 2012:604). Creswell (2014:40) further, reports that mixed method approach help one database to explain the other database and integrate quantitative and qualitative data reports. The results from the two phases of the study were then merged and discussed further for a greater understanding of the association between malnutrition and diagnosed drug susceptible TB in children aged zero to fifteen years old.

3.3.1. Population

The population for phase one of the study were all children's EMRs indicating that the child was treated for TB while less than fifteen years of age between 01 January 2008

and 31 July 2016 at BCMCF-SD in Mbabane city, Hhohho Region of Swaziland. A total population of 1500 EMRs for children were identified to be part of the population.

3.3.1.1 Sample

A sample is a finite part of a statistical population whose properties are studied to gain information about the whole population. This is regarded as a subset of the individuals in a population that the researcher is studying (Hanlon & Larget 2011:8). Therefore, the sample for the study were the children's EMRs that were randomly selected by the researcher using Microsoft excel formula for random selection.

3.3.1.2 Research setting

Phase one of the study was conducted in BCMCF-SD in Mbabane city of Hhohho Region of Swaziland. BCMCF-SD is the only paediatric and adolescent HIV/TB referral Centre of Excellence (COE) in Swaziland. BCMCF-SD offers comprehensive healthcare services to TB clients, HIV-infected children and their families. These services include care and treatment for HIV-infected and HIV-exposed children, adolescents and caregivers and treatment of common associated conditions such as TB and malnutrition (BCMCF-SD Report 2014/15:4).

Complicated HIV/TB cases of children and adolescents from the four administrative regions of Swaziland were referred for further care and management at BCMCF-SD. Therefore, the researcher was able to obtain data for children who were from both rural and urban environments of Swaziland and all the four administrative regions of Swaziland were represented.

3.3.1.3 Sampling

The sampling method for phase one of the research was simple random sampling, which was used by the researcher to extract the EMRs that represented the population of the EMRs of the children aged from zero to fifteen years old diagnosed with drug susceptible TB. Johnson and Christensen (2012:219) and Polit and Beck (2012:280) report that simple random sampling is the most basic form of random sampling to an extent that all the other types of random sampling use simple random sampling at some point in the

sampling process. In the context of this study, this kind of sampling also made sure that the EMRs had equal chances of being selected for quantitative data extraction.

All the EMR numbers of the 1500 children that were treated for TB at BCMCF-SD between the period of 1 January 2008 to 31 July 2016 were uploaded into Microsoft excel sheet and the researcher commanded Microsoft excel randomly to assign study number with a sequence from 001 to 306. The researcher, then deleted all EMRs that were not assigned study number in-order to remain with total of 306 EMRs. Therefore, data for the sampled EMRs were extracted from the EMR servers at BCMCF-SD.

3.3.1.3.1 Inclusion criteria of phase one

The inclusion criteria of phase one of the study were all the EMRs of all children who were initiated on Ant-TB Therapy (ATT) at BCMCF-Swaziland while aged from zero to fifteen years old, regardless of HIV status, TB outcome or nutritional support received. The EMRs also indicated clearly that the child was using susceptible TB drugs only. The sputum results of the child could either be tested negative for mycobacterium TB or positive. The positive sputum results would be considered if it had a sensitive drug susceptibility test (DST) results for the first line of ATT.

3.3.1.3.2 Exclusion criteria of phase one

The exclusion criteria for phase one of the study were all the EMRs of the children above fifteen of age. EMRs lacking information about ATT initiation and those which indicated that drug resistant TB treatment was initiated were excluded. The EMRs of children that were never diagnosed with TB nor treated for TB were also excluded.

3.3.1.4 Ethical issues related to sampling

All the extracted EMRs were exported to an excel database and each raw was assigned a random number using excel 2013. Then the same random values were copied and pasted to another column against each EMR number. The randomly assigned values were then used to select each EMR number by sorting them in an ascending order. The researcher then selected the first 306 EMRs from the ascending order to be the sample of the study.

3.3.1.5 Sample size

A sample size of 306 EMRs was included in the researcher's data analysis with regard to the following assumptions:

- A total of 1500 EMRs exist currently in the database warehouse,
- Confidence interval of 95%,
- Margin error of 5% and
- Distribution of 50% (Online sample size Raosoft calculator).

3.3.2 Data collection for phase one of the study

The data for phase one were a retrospective review of EMRs extracted from the BCMCF-SD, through assistance from the Baylor monitoring and evaluation (M&E) officer.

3.3.2.1 Data collection approach and method

Data for phase one were extracted from the BCMCF-SD EMR system. This phase of the study used a retrospective cohort, thus all former TB disease EMRs of children that started ATTs while less than fifteen years of age were identified by the researcher through the Baylor M&E Office from the period of 1 January 2008 to 31 July 2016. The researcher chose to start in the stated time above because TB unit at BCMCF-SD started operating in 2008 and 31 July 2016 was chosen because those who were initiated on ATTs on that date would be finished by mid-year of 2016. Thus, most of the variables that the researcher needed for phase one were available in the EMR system. Missing data were verified using the TB register.

3.3.2.2 Development and testing of the data collection instrument

The researcher designed an excel database to capture nutrition related variables thorough understanding of the research statement of the problem and readability of the variables in the EMRs that were included to be the population of study. An enhanced understanding of these issues through an extensive literature search and review was critical to set the pace for the development of a valid and reliable database (Johnson & Christensen 2012:163).

3.3.2.3 Characteristics of the data collection instrument

The researcher developed an excel database with the following minimum variables that were extracted from the EMR system at each of the visits included the age, height, weight, middle upper arm circumference (MUAC), GeneXpert (GXP); or sputum smear status, sputum culture status, haemoglobin (HB), HIV status and CD4 count. The data were cleaned and stored in an excel spreadsheet for further analysis in STATA version 14 by a statistician. Viral load (V/L) was not included, since it was only done for clients who showed symptoms of failing their anti-retroviral therapy (ART) regimen, thus most of the HIV-positive children were not tested for V/L.

3.3.2.4 Data collection process

The data extraction process was conducted from the EMR system of BCMCF-SD through the monitoring and evaluation (M&E) office. Missing data were obtained from the TB registers and the patients' white cards (document analysis). The data were captured into an excel spread sheet and cleaning and verifying completeness were conducted by comparing variables in the TB register and those in the EMR system.

3.3.2.5 Ethical considerations related to data collection

The researcher was guided by and adhered to the appropriate code of ethics, especially because the records of children under the age of fifteen years diagnosed with drug susceptible TB were reviewed (Polit &Beck 2012:172). The study approval letter was obtained from the senior management of BCM-CF-SD, the SSEC and the children's caregivers who voluntarily participated in the study post signing an informed consent. Permission to conduct the research was granted by the BCMCF-SD management through BCMCF-SD IRB and the SSEC. Please see Annexures B and D for the application letters to BCMCF-SD and SSEC.

The researcher obtained ethical clearance certificate to conduct the research from the UNISA Research Ethics Committee Department of Health Studies with the number: REC 012714-039 (NHERC).

3.3.2.5.1 Assent and consent for participants less than 18 years

The EMRs of the children were used in the first quantitative phase of the study. Missing information was verified through the TB register. Permission to extract the children's data and review the TB register was granted by the BCMCF-SD Executive Director, BCMCF-SD's IRB and SSEC. There was no interaction with human participant in this phase, thus there was no assent neither consent.

The research assistant was guided on how to handle research ethics two months before the commencement of phase two of the study. Phase one was a retrospective aspect of the research and there was no direct interaction with the children under fifteen years old diagnosed with drug susceptible TB. Privacy and confidentiality were maintained at a higher level, as the data were kept in a laptop that was locked in a strong room and it had a secret password that was known to the researcher and the research assistant only, who was trained on research ethics through an online training on research ethics offered by global health training centre in the following site: https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/. The researcher offered close supervision during the online training of the research assistant.

3.3.2.5.2 DATA SOURCES FOR THE STUDY

The EMRs for children less than fifteen years of age were used as data sources for phase one. Missing EMRs data were verified through the TB register. Prior to data extraction and reviewing of the TB register the researcher obtained permission from the BCMCF-SD Executive Director, BCMCF-SD's IRB and the SSEC.

3.3.2.5.3 Ethical considerations for field workers

The BCMCF-SD's M&E officer, who was the research assistant assisted the researcher to conduct the data extraction. The M&E officer is a qualified individual who holds a Bachelor of Arts Degree in Social Science from the University of Swaziland. He had more than ten years of work experience of handling research data.

3.3.2.5.4 The process followed to obtain approval to conduct the research

The approval to conduct the study was sought and obtained from the UNISA Higher Degrees Committee of the Department of Health Studies, Swaziland Scientific & Ethics Committee (SSEC) and BCMF-SD executive.

3.3.2.5.5 Confidentiality and anonymity

The researcher-maintained confidentiality and anonymity by making sure that participants' identity got protected at every stage of the research, by not linking the study unique codes to the EMRs' numbers. The unique code was known to the researcher and the research assistant only.

3.3.3 Data analysis

After the retrospective data were reviewed for completion then were kept safely in a laptop that was designated solely for the study. The laptop had a secret pin code known by the researcher and the research assistant. It was locked in a cabinet at BCMCF-SD strong room until data were given to the statistician for analysis (Coughlin Beauchamp & Weed 2009:85). Analysis was performed using STATA version 14. Categorical variables, (demographic information and TB outcomes) were presented using frequency and percentages and continuous variables were shown as mean and standard deviations. Comparisons between EMRs of TB/HIV co-infected and EMRs of TB only were accomplished by using Pearson's Chi-Square. Linear regression was then used to adjust for possible confounding factors to estimate an unbiased association for drug susceptible TB outcomes.

3.4 INTERNAL AND EXTERNAL VALIDITY OF THE STUDY

To enhance the internal validity and reliability of the study, the following measures were taken:

i. The validity for the study was enhanced since the objectives and the models of the study were supported by multiple and complementary types of data, that included both quantitative and qualitative data. The researcher was more confident about the validity study results (Polit &Beck 2012:604).

ii. Similar conditions for data extraction were ensured for each EMR that was selected

iii. The nature and purpose of the research were communicated in a language (SiSwati) that is understood well by study participants before enrolment into the study.

iv. The BCMCF-SD's internal research board (IRB), Swaziland Scientific and Ethics Committee (SSEC) and the University of South Africa (UNISA) Supervisors monitored the researcher closely throughout the research process to see if the researcher abided by the stated study protocol in the study.

3.5 FINDINGS OF THE FIRST QUANTITATIVE PHASE

The findings of phase one of the study significantly describe the clinical and demographic characteristics of malnutrition and the factors associated with malnutrition and diagnosed drug susceptible TB amongst children less than fifteen years of age in Swaziland. The association of malnutrition and TB disease outcomes in children less than fifteen years of age in Swaziland has been determined. It has also provided an evidence base for more comprehensive integration between nutrition programs, TB treatment programs and HIV programs. The findings are presented as per the following subtopics:

- Socio-demographic characteristics of the Children whose EMRs were selected
- Association between malnutrition and diagnosed drug susceptible TB
- Correlation between the confounding variables of malnutrition
- Other predictors of TB outcome (univariate logistic regression analysis).

3.5.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE CHILDREN WHOSE EMRS WERE SELECTED

A total of 306 EMRs of the children that were diagnosed with TB in the period of 01 January 2008 to 31 July 2016 were selected. This retrospective cohort consisted of (151/306) 49.3% males and (155/306) 50.7% females' representation. Categories of age groups during their start of TB treatment were (29/306) 9.48% for less than six months old, 45.75% for 6 to 59 months old, 25.43% for 5 to 10 years old and 16.34% for 11 to 15 years old. Mean age was 5.04, standard deviation 4.29 and the range was 0.12 to 14.8 years old. Table 3.1 below is the summary of the socio-demographic characteristics in relation to unfavourable TB outcomes.

Table 3.1: Socio-demographic characteristics in relation to TB outcomes

Characteristic	Favorable outcome	Unfavorable outcome			p-value
	Completed (n=246)	Discontinued (n=54)	LTFU (n=1)	Dead (n=5)	
Age					
0-6 months	15 (6%)	12 (22%)	1 (100%)	1 (20%)	
6-59 months	113 (46%)	25 (46%)	0	2 (40%)	0.001*
5-10 years	86 (35%)	8 (15%)	0	2 (40%)	
11-14.9 years	32 (13%)	9 (17%)	0	0	
Sex					
Female	125 (51%)	28 (52%)	0	2 (40%)	0.732
Male	121 (49%)	26 (48%)	1 (100%)	3 (60%)	
Geographic region					
Rural	123 (50%)	32 (59%)	1 (100%)	2 (40%)	0.435
Urban	123 (50%)	22 (41%)	0	3 (60%)	
Administrative regions					
Hhohho	186 (76%)	41 (76%)	0	3 (60%)	
Lubombo	18 (7%)	5 (9%)	0	0	0.213
Manzini	28 (11%)	6 (11%)	1 (100%)	2 (40%)	
Shiselweni	14 (6%)	2 (4%)	0	0	
Nutritional status					

Normal nutrition	114 (46%)	14 (26%)	0	3 (60%)	
Moderate malnutrition	84 (34%)	16 (30%)	0	0	0.002*
Severe malnutrition	48 (20%)	24 (44%)	1 (100%)	2 (40%)	
TB Type					
Extra-pulmonary	21 (9%)	2 (4%)	0	1 (20%)	0.466
Pulmonary	225 (91%)	52 (96%)	1 (100%)	4 (80%)	
History of TB treatment					
Newly on treatment	220 (89%)	46 (85%)	1 (100%)	5 (100%)	0.665
Previously treated	26 (11%)	8 (15%)	0	0	
HIV status					
Negative	49 (20%)	5 (9%)	1 (100%)	2 (40%)	
Positive	193 (78%)	48 (89%)	0	3 (60%)	0.156
Not tested	4 (2)	1 (2%)	0	0	

Table 3.1 indicated that both age and poor nutritional status at the time of TB treatment initiation of children diagnosed with drug susceptible TB at BCMCF-SD is significantly associated with unfavourable TB outcomes (P = 0.001). However, sex, geographical location, TB type, history of previous TB treatment, administrative region, and HIV status of the subject were statistically insignificant. The sex of the child obtained a p-value of 0.732, geographical location had a p-value of 0.435, TB type had a p-value of 0.466, history of previous TB treatment had a p-value of 0.665, and administrative region had a p-value of 0.213 and lastly, HIV status with a p-value of 0.156.

3.5.2 *Association between malnutrition and diagnosed drug susceptible TB*

Clinical variables that were considered in the study were anthropometrics measurements that included weight for height z-score (WHZ), age for height z-score (AHZ) and MUAC, HIV status and immunological status as per CD4 count categories. Studies have indicated the mentioned variables as confounding factors that contribute to poor TB outcome. The WHZ-score was used to measure the level of wasting for the children who were started at TB treatment at BCMCF-SD. AHZ-score intended to measure the level of stunting at the time of TB initiation for all the children whose EMRs were selected for review. MUAC was used to assess the level of acute malnutrition.

The results of the study indicated that both moderate and severe malnutrition (wasting) were significantly associated with unfavourable TB outcomes (P=0.001) amongst children aged zero to fifteen years of age in Swaziland. However, moderated and severe stunting were indicated to be insignificantly associated with poor TB outcomes.

In addition to that, both the positive HIV status and history of TB status were found to be contributing factors to poor nutrition and both had a P value of (0.001). Table 3.2 below is the summary of the distribution of the child characteristics by nutritional status:

Table 3. 2: Distribution of child characteristics by nutritional status

Characteristic	**Nutritional status**			**p-value**
	Normal nutrition (n=131)	**Moderate malnutrition (n=100)**	**Severe malnutrition (n=75)**	
Age				
0-6 months	0	5 (5%)	24 (32%)	
6-59 months	9 (7%)	80 (80%)	51 (68%)	<0.001*
5-10 years	82 (63%)	14 (14%)	0	
11-14.9 years	40 (31%)	1 (1%)	0	
Sex				
Female	76 (58%)	47 (47%)	32 (43%)	0,071
Male	55 (42%)	53 (53%)	43 (57%)	
Geographic region				
Rural	63 (48%)	57 (57%)	38 (51%)	0,399

Urban	68 (52%)	43 (43%)	37 (49%)	
TB Type				
Extra-pulmonary	12 (9%)	6 (6%)	6 (80%)	0,675
Pulmonary	119 (91%)	94 (94%)	69 (92%)	
History of TB treatment				
Newly on treatment	106 (81%)	92 (92%)	74 (99%)	<0.001*
Previously treated	25 (19%)	8 (8%)	1 (1%)	
HIV status				
Negative	9 (7%)	26 (26%)	22 (29%)	
Positive	121 (92%)	72 (72%)	51 (68%)	<0.001*
Not tested	1 (1%)	2 (2%)	2 (3%)	

3.5.3 CORRELATION BETWEEN THE CONFOUNDING VARIABLES OF MALNUTRITION

The researcher used the formula shown below to calculate the correlation between the confounding variables in STATA version 14.

"Formula = spearman Age_ Group MUAC CD4_at_Initiation TB_ Site baseline_ haemoglobin height z score weight z score, star (0.05) obs =306".

Table 3.3 displays the correlation between the confounding variables of malnutrition in children less than 15 years old diagnosed with drug susceptible TB in Swaziland. Variables that have a positive strong correlation are highlighted in red and those with strong negative correlation are highlighted in green. The researcher discovered that age has a strong positive correlation with wasting, stunting, MUAC, Baseline HB and a weak correlation was observed on the site of TB (pulmonary/extra-pulmonary TB).

The CD4 count of the children was observed to have a strong negative correlation with age, wasting, stunting and MUAC. However, the site of TB was observed to have a very low correlation with all the selected variables. Table 3.3 below Showing the spearmen correlation the children's variables

Table 3.3: The spearmen correlation the children's variables

Variables	*Age*	*wasting*	*stunting*	*Baseline HB*	*MUAC*	*Initiation CD4*	*TB site*
Age	1						
wasting	0,89844	1					
stunting	0,912604	0,876615	1				
Baseline HB	0,146373	0,214686	0,15924	1			
MUAC	0,262268	0,203908	0,237954	-0,02103	1		
Initiation CD4	-0,51591	-0,42155	-0,47026	-0,07254	-0,12148	1	
TB site	0,059386	0,070423	0,049658	-0,03264	-0,0163	-0,0017739	1

3.5.4 OTHER PREDICTORS FOR POOR TB OUTCOME

In the study it has been found that both the age of children less than five years at the time of TB diagnoses and severe malnutrition were strongly associated with poor TB outcomes with p-values of 0.001 and <0.001, respectively. The sex of the child, geographic location, administrative region, type of TB and HIV status at the time of TB diagnoses were found to be not good predictors for poor TB status. Table 3.3 summarizes the study findings in relation to the other predictors for poor TB outcomes amongst children aged less than 15 years old diagnosed with drug susceptible TB in Swaziland.

Table 3.4: Predictors of TB outcome (univariate logistic regression analysis)

Characteristic	OR (CI)	p-value
Age		
0-6 months	3.9 (1.7-9.1)	0.001*
6-59 months	1	

5-10 years	0.5 (0.2-1.1)	0.07
11-14.9 years	1.2 (0.5-2.8)	0.71
Sex		
Female	1	
Male	1.03 (0.6-1.8)	0.91
Geographic region		
Rural	1	
Urban	0.7 (0.4-1.3)	0.25
Administrative regions		
Hhohho	1	
Lubombo	1.2 (0.4-3.3)	0.76
Manzini	1.4 (0.6-3.1)	0.46
Shiselweni	0.6 (0.1-2.8)	0.51
Nutritional status		
Normal nutrition	1	
Moderate acute malnutrition	1.3 (0.6-2.7)	0.51
Severe acute malnutrition	3.8 (1.8-7.6)	<0.001*
TB Type		
Extra-pulmonary	1	
Pulmonary	1.8 (0.5-6.2)	0.37
History of TB treatment		
Newly on treatment	1	
Previously treated	1.3 (0.6-3)	0.54
HIV status		
Negative	1	
Positive	1.6 (0.7-3.6)	0.24
Not tested	1.5 (0.2-15.5)	0.71

3.6 CONCLUSION

This chapter discussed the methodological issues of the study in phase one, including the study design sampling procedures and validity and reliability of the study. Discussion of the ethical issues of the study was also included. The results were the socio-

demographics and clinical characteristics of the children whose EMRs were selected for the study, association between malnutrition at the time of TB diagnosis and TB outcomes and the other factors that contribute to poor TB outcomes amongst the children less than 15 years old diagnosed with drug susceptible TB. The next chapter presents the methodology and the results for phase two of the study.

CHAPTER 4

RESEARCH DESIGN, METHODS AND RESULTS OF PHASE TWO

4.1 INTRODUCTION

This chapter reports on the research design and methodology of phase two of the study. The objective of the qualitative phase of the study was to explore and describe the perceptions of the children's caregivers with regard to paediatric nutrition before, during and after TB treatment.

Therefore, this phase outlines the steps taken when conducting the qualitative phase of the study. These included the application of an appropriate research design, and consideration of study population, sample selection, scientific rigour, data collection, ethical considerations, qualitative data analysis and the results of the second qualitative phase of the study.

4.2 RESEARCH DESIGN

A research design is a plan detailing and justifying how a research was conducted and it guides the researcher in planning for and implementing a study (Kumar 2011:327). The study design for this phase is a narrative study design following a qualitative approach.

4.3 RESEARCH METHOD

After reviewing the results of phase one of the study the researcher used purposive sampling to select the study participants, which were caregivers for the children whose EMRs were reviewed. Individual consent was obtained from each participant and semi-structured individual interviews were conducted to collect data using SiSwati language or English language depending on the choice of the study participant. All the participants were able to speak both languages, but most of them preferred to be interviewed using the SiSwati language. The research assistant assisted the researcher by taking notes during the interview and each of the interviews was recorded using a digital voice recorder.

After recording an interview, the digital voice recorder and the interview notes were locked in a cabinet holder in one of BCMCF-SD's strong room. Both the digital voice recorder and the interview notes were kept secured and were taken by the researcher for data transcribing at the end of all the interviews. The data were transcribed at BCMCF-SD private room where only the researcher and the research assistant were allowed entry to that room during the transcribing and the data analysis processes. The data were analysed using NVIVO version 11. Kean University (2012:35) reports that instruments used for the study were kept under lock and key for at-least five years and thereafter destroyed.

The researcher observed all the ethical principles outlined in the University of South Africa Research (UNISA) Policy as well as the universal ethics principles. Ethical approvals were obtained from the UNISA Research Ethics Committee Department of Health Studies, SSEC and BCMCF-SD IRB.

4.3.1 Population

The population for phase two of the study were all the caregivers of the 306 children diagnosed with drug susceptible TB whose EMRs were extracted in phase one of the study. The caregivers' ages ranged between 18 to 65 years old.

4.3.1.1 Sample

In phase two of the study purposive sampling was employed by the researcher to select, recruit and enroll the caregivers from the population that met the inclusion criteria for semi-structured interviews. The ages of the children's caregivers ranged between 18 and 65 years. Johnson and Christensen (2012:219) and Babbie (2013:129) state that purposive sampling is sometimes called judgmental sampling, because the researcher pre-specifies the characteristics of the population of interest and purposefully locate who suits those characteristics.

The researcher was able to purposefully select study participants who were judged to be typical of the population and were particularly knowledgeable about the issues under study, which is the nutritional state of the child during TB treatment. The sampling in the study was in a subjective manner and it provided no external, objective method for assessing if the selected participants were typical (Polit & Beck 2012:279).

Phase two of the study included the children's caregivers with the following characteristics:

- Age range between of 18 to 65 years old.
- The caregivers of the children whose EMRs data were extracted in phase one of the study.
- The caregivers of the children who started ATTs between the periods of 1st January 2014 to 31st July 2016. The researcher chose the 2014 to 2016 period to avoid the risk of the caregivers forgetting the key information and due to the fact that most of the children are discharged from BCMCF-SD after two to five years of enrolment.
- The caregiver had cohabited with the child at-least six months before being diagnosed with TB, during treatment and at-least six months after completion of ATTs. Such caregivers included the biological parents, grandparents, aunts, uncles, siblings, or relatives through marriage, orphanage caregivers, direct observed therapy (DOT) supporter and guardians irrespective of sex.

4.3.1.2 Ethical issues related to sampling

Martínez-Mesa, González-Chica, Duquia, Bonamigo and Bastos (2016:327) report that sampling is a process through which participants are selected from the sample frame. They further stated that the sampling strategy needs to be specified in advance, given that the sampling method may affect the sample size estimation. When there is no rigorous sampling plan the estimates derived from the study may be biased. Therefore, the researcher minimized the biasness by reducing selecting the sampling frame in advance and followed it during the selection of the study participants. Only participants that met the inclusion criteria were sampled for the semi-structured interviews.

4.3.2 Data collection

The researcher obtained qualitative data by conducting semi-structured interviews with the children's caregivers during routine follow-up visits and/or in the caregivers' home. The researcher collected data at home from caregivers that had their files closed at the study sites due to completion of the TB treatment and those that were transferred to nearest clinic after they got clinically stable after TB/HIV treatment initiation. Therefore,

the researcher wanted to eliminate cost for participating in the study and minimize the time that the participant can spend in the study. Potential participants who were reporting to be in a hurry during their clinic visit were also given an option to be interviewed at their homes on a date and time that the they regarded as suitable for them. The researcher only visited one home at a time and kept the data in a secured room and locked cabinet at BCMCF-SD. No identifying information for the caregiver and the child was attached to the collected data. Unique codes were applied, and they were known by the researcher and the research assistant only.

4.3.2.1 Data collection approach and method

The researcher had one research assistant to assist with the data collection during the interviews of the caregivers. The researcher further trained the research assistant on human research for a period of one week. This involved close supervision, orientation on the study protocol, and discussion of key ethical issues related to the study. The research assistant took a free online training on research ethics offered by Global Health Training Centre (GHTC) in the following site: https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/, at-least one month before the data collection begun.

4.3.2.2 Development and testing of the data collection instrument

A consent form, information sheet and an interview guide were developed in English language and translated to SiSwati. One month before to the qualitative data collection, the consent form, information sheet and interview guide were pretested at BCMCF-SD with five practice participants (two poor TB outcomes and the other three good TB outcomes). The Centre for evaluation and research (2011:1) confirms that pilot testing enables the researcher to be sure that every study participant understands the interview the same way. According to Polit and Beck (2012: 59), the researcher who does piloting, is also able to identify if any of the questions made respondents feel uncomfortable. The researcher was able to find out how long it took to complete the study interview in real time. The interviews took an average of 38 minutes per participant.

4.3.2.3 Characteristics of the data collection instrument

The data collection instruments included the consent form, information sheet, semi structured interview guide and a digital voice recorder. The consent form was one page

long and information sheet three pages long. A digital voice recorder was used to record the interviews and the research assistant was writing field notes during the entire interview of each study participant.

4.3.2.4 Data collection process

Firstly, the caregivers that met the inclusion criteria were purposively selected and contacted through phone calls to make an appointment whether at home or to meet the researcher during clinical visits. After honouring the appointment, the researcher, research assistant and the participant could meet in a private room, where translated information sheet and consent form were given to the participant to read and the researcher or research assistant could assist the participant to read the consent form and information sheet.

All questions that arose were addressed in a language that was understood and preferred by the participant, namely English and SiSwati. The participant was then given a chance to sign the consent form in the presence of the researcher and the research assistant. Both the researcher and the research assistant signed as witnesses. The interviews were conducted by the researcher and the research assistant took short notes and monitoring the digital voice recorder to ensure that it recorded the entire interview.

4.3.2.5 ***Ethical considerations related to data collection***

The researcher was guided and adhered to the appropriate code of ethics throughout the study (Polit & Beck 2012:172). Study approval letters were obtained from the senior management of BCM-CF-SD, BRAIN, the SSEC and UNISA Research Ethics Committee Department of Health Studies. The children's caregivers voluntarily participated in the study after signing an informed consent form. The permission to conduct the research was granted by the BCMCF-SD management depending on the approval by their IRB and the SSEC.

Please see Annexures A, C and E for the approvals from UNISA Research Ethics Committee Department of Health Studies, BCMCF-SD and SSEC. The researcher maintained the principles of confidentiality, respect and beneficence throughout the data collection (Department of Health 2014:1). Each of the mentioned research principles are discussed below:

4.3.2.5.1 Rights to confidentiality and privacy

The researcher and the research assistant-maintained confidentiality with regard to the information obtained from each of the participants. Confidentiality was achieved by removing personal identifiers like names and phone numbers from the collected data. The participants' identities were not revealed to anyone else, other than the researcher and the research assistant. Privacy was maximized by controlling other people's access to the collected data. The data were locked in a cabinet in one of Baylor strong rooms. Literature reveals that respecting the privacy of research participants is at the heart of the conduct of research (Johnson & Christensen 2012:63).

The researcher conducted the interviews in a place and time that were convenient to the participants, while data management, analysis and reporting were handled in a way that no other person would be able to link the descriptions to individual participants. The researcher did not collect any other data outside of the scope of the study and all the participants were treated equally during the interview process. Participants' names were substituted with codes in the interview transcripts and the audio recordings were strictly handled by the researcher.

4.3.2.5.2 Respect for person

This principle stressed the voluntary nature of the participation to the research project. It is argued that research participation must be completely voluntary and the participants should be well informed and understand what is involved in the study (Babbie 2013:63). The autonomy of the participants was ensured through informed consent. The information about the study was given to the participants in verbal and written forms using a language that was preferred by the participant. Verbal information was given to the participants during the first contact while written information was contained in the participant information sheet attached to the consent form.

The researcher reviewed the information sheet with the participants before the interviews. Each participant was offered the opportunity to ask questions for clarification. The participants were also informed about their rights to withdraw from the study at any time. They were assured that refusing to participate or withdrawing from the study would have

no adverse effects on them as the researcher was working in the same setting. Thereafter, they were requested to sign the written consent form.

4.3.2.5.3 Beneficence

According to Kumar (2011:221) harm includes not only hazardous medical experiments, but also any social research that might involve such things as discomfort, anxiety, harassment, invasion of privacy or demeaning or de-humanizing procedures. The study did not cause physical nor psychological harm to the participants. The researcher ensured that interview questions were carefully phrased and that participants were offered an opportunity to ask questions at the end of the interviews.

In addition, the researcher was cognisant of the risk of TB/HIV-related stigma. In order to avoid the potential for TB/HIV-stigmatization, the researcher exercised confidentiality with regard to the TB/HIV status of the child. Participants' consent form did not include the TB/HIV status of the participants or the status of the child.

4.3.3 Data analysis

The data management and analysis started at the time of the data collection process. Data management as the first step of data analysis involves transcribing, organizing, developing categories and coding data (Stuckey 2014:3).

Transcription of data was done after all the research interviews had been conducted. Transcription of data assisted the researcher to revisit the entire data and to organize the data. Field notes of non-verbal communication codes, such as nodding, silence, and other body language were also added to the transcripts.

The researcher transferred the recorded audio data onto a laptop computer, while an ear piece was used to listen to each participant's data. This was done to compare it to the written documents. The researcher made all the necessary corrections and kept the same codes that were used on the original manuscripts. The capturing and typing of data were done according to the order of questions on the interview schedule and related probing questions.

After capturing data into micro-soft word, the researcher created folders corresponding to the recordings. Each of the transcripts was translated from SiSwati to English. Information in each folder was further organized and captured into a table format. The participants' answers with the corresponding code were captured in the first column. The participants' answers were copied from their transcribed manuscripts and pasted into this column with the probing questions.

Thereafter, the researcher reviewed the documents and proceeded with cleaning the data. Data analysis using Nvivo version 11 started after the cleaning process. The researcher used the thematic content approach as a framework to guide the data analysis process. Following the cleaning of data, the researcher studied the data in order to identify concepts that emerged from data by using the inductive approach. Similar concepts were placed into one category in the Nvivo. The quotes from which the concept emerged were also dragged and served in Nvivo for quick reference.

At the end of that exercise, the identified concepts were copied and pasted into a table. Similar concepts were grouped together in a different table. The occurrences of each concept were counted. The groups of concepts were examined to derive possible subthemes, which were captured in a different column and each sub-theme was captured with the emerged concepts as shown in table 4.2 to follow on page 47.

4.4 SCIENTIFIC RIGOUR

The researcher ensured scientific rigour of the qualitative phase through trustworthiness as evidenced by credibility, transferability, dependability, conformability and authenticity of the data (Polit & Beck 2012:584-585). Each of these steps of ensuring trustworthiness are explained below:

Credibility refers to confidence in the truth of the data and its interpretations. The researcher observed the two aspects of credibility by carrying out the study in a way that enhances the believability of the findings and secondly, taking steps to demonstrate credibility in research reports (Polit & Beck 2012:585). This was achieved by confirming the evaluation of conclusions by participants and minimized any sources of bias. Also, the researcher quoted exactly what was verbalized by the participants.

Transferability is defined as the potential for extrapolation, that is, the extent to which findings can be transferred to or has applicability to other settings or groups. The researcher provided sufficient descriptive data, so that consumers can be able to evaluate the applicability of the data to other contexts (Polit & Beck 2012: 585). Transferability in the study was ensured by providing detailed descriptions of the participants' characteristics, the participants' description of the phenomenon, as well as the researcher's observations in reporting the findings.

Dependability is concerned about the stability of data over time and conditions (Polit & Beck 2012:585). The researcher gathered evidence from the literature to support the findings and provided a thorough documentation of all findings.

Conformability is concerned with establishing that the data represent the information participants provided and that the interpretations of those data are not invented by the inquirer (Polit & Beck 2012:585). The researcher limited any sources of biasness and provided unbiased interpretation of findings by citing the exact words of the participants and use of existing literature to control the results. The researcher was assisted by the supervisor and independent coding was done using NVIVO version 11.

Authenticity refers to the extent to which researchers fairly and faithfully show a range of realities. Authenticity emerges in a report when it conveys the feeling and tone of participants' lives as they are lived. A text has authenticity if it invites readers into vicarious experiences of the lives being described and enables readers to develop a heightened sensitivity to the issues being depicted (Polit & Beck 2012:585). Therefore, the researcher demonstrated the feeling and the tone of the participant's lives as they are lived by conducting the research within participants' natural and everyday environments.

4.5 THE RESULTS FOR THE QUALITATIVE PHASE OF THE STUDY

Data saturation was reached after 12 interviews were conducted and the researcher stopped the interviews. In this section, the researcher presents and discusses the main results. The results are presented according to the objective that is related to the qualitative enquiry, which was to explore and describe the perceptions of the children's caregivers with regard to paediatric nutrition during TB treatment. The first sub-section describes the characteristics of the participants. The second and third sub-sections

present the main findings related qualitative objective of the study. The researcher used the extracts from the participants' descriptions and existing literature to control and support the results. The researcher maintained the exact language and phrases that were used by the participants, but some grammatical amendments were made in order to maintain the logical flow and clarity of discourse.

4.5.1 CHARACTERISTICS OF THE PARTICIPANTS

The participants were described according to the following variables: age, marital status, highest level of education and employment status. Table 4.1 summarizes the characteristics for research participants.

Table 4.1 Characteristics of the participants Variable			
Variables	Category	Frequency	Percentage (%)
Age:	18- 29	2	16.7
	30-39	4	33.4
	40-49	5	41.7
	50-65	1	8.3
Marital Status	Married	5	41.7
	Single	2	16.7
	Widowed	5	41.7
Level of Education	Primary Education	3	25
	Secondary Education	4	33.4
	High School	3	25
	Tertiary Training	2	16.7
Employment Status	Employed	3	25
	Unemployed	8	66.7
	Self Employed	1	8.3

Employed family members	0	4	33.3
	1	5	41.7
	2	2	16.7
	3	1	8.3
Number of Children in the family.	1 to 2	3	25
	3 to 4	4	33.3
	5 to 6	4	33.3
	7 to 10	1	8.3

The study participants consisted of females only. The age range for the participants was between 18 and 65 years. The majority was aged between 40 to 49 years, while only one was between the aged of 50 to 65 years old. Two were single, five were married and the other five were widowed. All the participants had received some form of education and most of them reached secondary school and minority reached tertiary. Only one of the participants was self-employed, three employed and most of them were unemployed. However, all the families had at-least one employed family member. Most of the families had more than three children to feed and only one had one child.

4.5.2 The perceptions of the children's caregivers

The study participants were asked questions relating to their perceptions regarding the child's nutritional situation during the course of the TB treatment. Ten sub-categories were derived from the thematic content analysis of the descriptions provided by the participants. Two themes emerged and were classified into four categories. Table 4.2 provides a summary of these themes, categories and the sub-categories. Discussions are included at the end of each theme.

Table 4.2. The perceptions of the children's caregivers		
Themes	**Category**	**Sub-Categories**
		1.1.1 Lack of balanced diet

1. Nutritional situation at home	1.1 Nutrition for the child	1.1.2 Mixed feeding during breastfeeding period
	1.2 Social environment	1.2.1 Death
		1.2.2 Lack of food due to unemployment
		1.2.3 High number of children than what the family could afford
2. Nutritional support from the health care facility	2.1 Food by prescription	2.1.1 Plumpy nut supplies
		2.1.2 Food by prescription supplies
		2.1.3 Sharing of the food supplies
	2.2 Health education	2.2.1 Health education too long
		2.2.2 Poor adherence to the ATTs

THEME 1: NUTRITIONAL SITUATION AT HOME

This theme reflects the participants' perceptions regarding a child's nutritional situation at home. The nutrition of the child and the social environment during the period of TB treatment emerged as categories. Two categories emerged under the two themes and two sub-categories emerged under the category of nutrition for the child.

CATEGORY 1.1: NUTRITION FOR THE CHILD

As indicated in Table 4.2, Lack of a balanced diet and mixed feeding during breast feeding period were the two sub-categories. These sub-categories reflect the participants' views and feelings regarding the nutrition provided to the children during the period of TB treatment.

Sub-category 1.1.1: Lack of balanced diet

All the 12 participants complained of lack of a balanced diet at their homes. They assumed that the children contracted the TB because they did not have a balanced diet. These views were exemplified by the extracts below:

"Actually, the child could rarely get a balanced diet. The only food I was able to give to her was porridge. I was affording beans and sour milk maybe twice a week" Participant 3, 7, 8 & 10.

"We do not know where to get the balanced diet. Considering that we are at these rural areas and the beans were finished. When it is winter time it is difficult for us to get any green food stuff" Participant 1, 4 & 5.

"It is painful when you see you own children eating porridge alone, yet nothing you can do to alleviate the situation. I know it is not health but they should eat just to fill the stomach" Participant 2, 6, 9, 11 & 12.

Literature reveals that inadequate nutrition is one of the major risk factors related to the current epidemic of diseases (Corrêa, Vencato, Rockett & Bosa 2017:554). The perceptions brought by the participants agree with existing research that shows that malnutrition is a predictor of tuberculosis and is associated with worse TB outcomes and poor TB outcomes (Jaganath & Mupere 2012:1809).

Sub-category 1.1.2: Mixed feeding during breastfeeding period

Four caregivers were taking care of breastfed children and all the four children were reported to be mix-fed. Thus, they assumed that the children were not well-fed as some of the mothers would come home late and be very tired from work. One of these caregivers was a non-biological caregiver, who also reported that the mother of the child was an alcoholic. Their views were expressed as follows:

"I raised this child by myself. Her mother was a drunkard. She used to knock off and go to drink alcohol and come home very drunk, at times unable to breast feed the child" Participant 2, 6, 8, 9, & 12.

"I do not think the child was getting enough food. As much as her mother was breast-feeding her and giving formula feeding, there was a time whereby the mother could lack money for the formula feeding. Thus, I used to feed that child

with the family meal when she is at work. The situation became worse after the death of the mother" Participant 1, 3, 9, 11 & 12.

Despite world-wide recommendations, the majority of mothers do not practice breast-feeding exclusively for six months post-delivery. The reasons for not practicing EBF are diverse and include advice or social pressure to mix-feed, perceptions of inadequate milk supply, need for water supplementation, societal feeding norms and lack of adequate knowledge on breast-feeding and health (Marquis, Lartey, Perez-Escamilla, Mazur, Brakohiapa & Birks 2016:115). Considering the results from the participants of the study, one can tell that the socio-economic situation of the mothers was the main influence for the mixed feeding, which was said to be the cause of malnutrition, hence the active TB disease. Palmeira and Carneiro-Sampaio (2016:584) state that breastfeeding protects infants against infections mainly via Secretory immunoglobilin A (SIgA) antibodies, but also via other various bioactive factors. The infections may include, but not limited to TB, HIV/AIDS and meningitis.

CATEGORY 1.2: SOCIAL ENVIRONMENT

This category reflects the participants' views and feelings regarding the social environment around the child during the period of TB treatment. As indicated in Table 4.2, three sub-categories were derived from the thematic content analysis of the participants' descriptions of their perceptions with regard to paediatric nutrition during TB treatment. They felt that the social environment that the children were exposed to was not conducive for them to remain healthy as described below:

Sub-category 1.2.1: Death

A child of one of the participants was reported to have died and one caregiver had died a few months before her child was diagnosed with TB. After the death of the parent the child was deprived of nutrients that could be obtained from breast milk. Studies indicate that breast milk, protein and micronutrients play significant roles in the development of innate and cell-mediated immunity and that these factors are critical for response against TB (Jaganath & Mupere 2012:1811). The WHO guidelines further reports that undernutrition at the time of diagnosis of active TB is a predictor of increased risk of death (WHO 2013:1). Her words were captured as stated below:

"I think the death of the father led to the death of the child, because it was immediately after his death that the child was diagnosed with TB. Then, myself as her mother I was left alone to take care of this child, yet I was also depressed. There was no enough food in the house and I was unable to produce enough breast milk. The mother of this child died few weeks post-delivery and I do not think the child could survive". Participant 10.

"I am happy that my child survived, but I noticed that after the death of the breadwinner (whether that mother or the father) most of the children in the village were developing TB" Participant 2, 5 & 7

Studies have revealed that childhood TB indicates a recent infection, particularly in children aged less than five years old. This is considered a sentinel event insofar as it highlights the presence of an undiagnosed or untreated source case (Lancella, Veccihio, Chiappini, Tadilini, Cirillo, Tortoli, Martino, Guarino, Principi, Villani & Esposito 2015:1) and (Caminero & Scardigli 2016:282). A study conducted by Baylor Swaziland also reported that prioritizing children contact tracing contributes to overall TB case detection due to the recent infection on the child. The children progress faster from TB infection to TB active disease due to a number of factors that include weak immune system (Mandalakas, Ngo, Ustero, Golin, Anabwani, Mzileni, Sikhondze, & Stevens 2017: 2).

Sub-category 1.2.2: Lack of food due to unemployment

All the family members explained that they felt that unemployment was a contributing factor to the lack of enough food for the children. Even those that were mixed fed, sometimes could run out of formula milk, thus forced to eat family meal, which is mostly composed of starch. The following are the views that were shared by all 12 participants:

"The unemployment rates are very high in this country. I have completed form five and when looking for a job, there is none that I am getting" Participant 1, 2, 7, 9, 11 & 12.

"There are no jobs for us outside there! That is why we and our children become the victims for such infections" Participant 3, 5, 7 & 10.

"The escalating cases of TB is a result of lack of jobs. We are force to squatter in one room with the TB patients" Participant 4 & 8.

The results of the study are congruent to the fact raised by WHO that lack of food led to malnutrition which has proved to be a risk factor for progression from TB infection to active TB disease (WHO 2013:1). The results also concur with a report by World Food Program (WFP), which states that Swaziland ranks 47 out of 78 developing countries in the Global Hunger Index (GHI), showing a decline in food security since 1990. High dependence on rain-fed maize production in dry areas, very low income levels of rural smallholders and high prices of food and agricultural inputs together with high rates of HIV and AIDS among wage earners combined with unemployment are the main drivers of food insecurity (WFP 2016:3). Khumalo and Eita (2015: 1190) report that in 2007 and 2010, the official unemployment rates in Swaziland reached 40.6% of the labour force ages 15 and above. Gebreweld, Kifle, Gebremicheal, Simel, Gezae, Ghebreyesus, Mengsteab and Wahd (2018:38) continue to report that some patients lose their job when their diagnosis is known and are too ill to continue working or unable to find daily work due to time-consuming treatment arrangements.

Sub-category 1.2.3: High number of children than what the family could afford

Most of the families felt that they had many children to feed than what they could afford, with the exception of one family that reported that they had only one child and they thought they could afford. Sometimes, the children came from the extended family, while others came from their neighbours. They said the following during the interview:

"Actually, where I stay there are a lot of children from the neighbourhood homestead. They come and play with my kids and then I have to feed all of them. Some of these children are very poor and vulnerable" Participant 1, 4, 5 10 & 12.

"You know, in these extended families, one is forced to feed children that he or she have not budgeted for. Some of us cannot afford high number of children" Participant 2, 3, 8, 9 &11.

The results of the study agree with the fact that Swaziland faces numerous challenges including poverty, chronic food insecurity and HIV/AIDS. About 63% of Swazis live below

that national poverty line and 52% of the national population under the age of 20. 45% of children less than 15 years old are orphaned and vulnerable (WFP 2018:2).

THEME 2: NUTRITIONAL SUPPORT FROM THE HEALTH CARE FACILITY

This theme reflects the participants' views and feelings about the nutritional support that the children received during the course of the treatment. As illustrated in Table 4.2, the theme includes two categories and five sub-categories:

CATEGORY 2.1: FOOD BY PRESCRIPTION

Food by prescription refers to food packages that are prescribed by a qualified health care worker after making proper assessment of the child's nutritional status.

Sub-category 2.1.1: Plumpy nut supplies

Most of the caregivers reported that they received plumpy nut for their children. They shared the plumpy nut with the other children at home, since they were all hungry. The plumpy nut could hardly last for the period, which it was prescribed for. At times the plumpy nut was reported to be out of stock.

> *"Yes, I did receive the plumpy nut and it was very helpful. It used to feed all of us, as it makes good peanut butter" Participant 1, 3, 7, 9 & 10.*

> *"The plumpy nut used to be very nice for my boy, but from time to time it was reported to be out of stock" Participant 2, 4, 5, 9 & 12.*

The results of the study are comparable with those of other studies that have been conducted in other poor resource settings like Swaziland. According to Tuffs University (2012:8), the provision of plumpy nuts in addition to treatment brings good results with regard to patient improvement from malnutrition and speed recovery of the immune system.

Sub-category 2.1.2: Food by prescription supplies

Some of the older children between 12 to 15 years were reported to have received food by prescription. The food by prescription included one bag of maize, two liters of cooking

oil, Soya meal and five kilograms of beans. They all reported that there were times when the food by prescription was reported to be out of stock or one package like been reported to be out of stock.

> *"This is a good initiative that the government is doing and it is helpful. But these food packages were sometimes out of stock in a time that we needed them the most" Participant 1, 3, 8.*

> *"There were times that the food by prescription packages were reported to be out of stock in the unit and that was painful. The most painful part was that one would be referred to the hospital, paid the least money with the hope that he or she would get the food, but be told that there was no food" Participant 2, 4, 6, 7, 9, 11, 10 & 12.*

The results of the study indicate that the caregivers acknowledge the nutritional support they received from the health facilities. However, due to high numbers of children that were enrolled on the program, the food often got out of stock (National Disaster Management Agency (NDMA) 2016: 21). A pilot study conducted in 2010 at the capital city of Zambia, Lusaka by a by a Roman Catholic Organisation also indicates that there was no consistence in the supply of the food to the eligible clients in health facilities due to a number of factors that include lack of space, poor stock management and integration of services (Catholic Relief Services 2012:8).

Sub-category 2.1.3: Sharing of the food supplies

Both the plumpy nut and the food by prescription were not taken as therapy for the sick child only, but a meal for the family. In some families the plumpy nut was used as peanut butter for the family, yet others would share amongst all the children. Food by prescription was shared amongst family members. Only two reported that they sold the food packages along the way from the health facility since they needed money. The statements below depicts the words of the participants:

> *"The food packages were benefiting all of us in the family, such that we suffered from hunger when it was stopped to be supplied. When we run out of money, we use to sell it, so that we can buy meat" Participant 1, 2, 10 & 12.*

"Nothing could be done sir, but to share the food amongst the children. My children used to love it so much such that even today they ask me to go and fetch if from the clinic" Participant 3, 6, 7, 8, 11.

A study conducted by the School of Public Health (SOPH) in Ethiopia, Addis Ababa, reports similar results to the results of the study as shown by the participants' verbatim above. The level of adherence to the food supplies from the health facility was found to be at 36.3%. Some clients were sharing the food amongst their families, while others sold the food supplies (Kabede & Haidar 2014:1). As the food supplies are shared with other the TB patients find themselves running of essential nutrition and defaulting the TB treatment. (Gebreweld, et al 2018:38).

CATEGORY 2.2 HEALTH EDUCATION

Health education on promoting public health is very essential for all participants that receive care (Kemppainen, Tossavainen & Turunen 2013:491). As illustrated in Table 4.2, health education too long and poor adherence to ATTs emerged as sub-categories of this category.

Sub-category 2.2.1: Health education too long

All 12 participants appreciated the health education they received, though they all complained that it is long and difficult to remember. They said the following:

"The health education that I received was very helpful, but I did not have a copy of the key messages that I could use to remind myself. The education was covering a lot of things that we could fail to remember when we reached home. We were not given even a document that we could use to remind ourselves" Participant 2, 6 & 12.

"You know my child….. We are very old now. The information was too much for some of us to remember. It would be better that the older children can be called periodically to teach there like those that come for HIV support groups. Empowering the child is better than empowering us. The education on HIV, TB,

Nutrition, medication and other illnesses becomes long to be given on one day" Participant 1, 2, 7, 9 & 11.

In the year 2010, a study was conducted by the Department of Community Health in Northern Nigeria which indicated similar results to those of the current study. The study indicated that the amount of time that the patient spent in a health institution is crucial, since it affects the utilisation of health care services. Some patients develop poor adherence tendencies to the scheduled clinical visits due to long patient waiting in the health facilities (Umar, Oche & Umar 2011:79). Literature also states that prolonged waiting time at the health facility to get medical services was significantly associated with non-adherence to anti-TB treatment (Tesfahuneygn, Medhin & Legesse 2015:4). Ballard (2010:1409) further reports that aging is highly associated with forgetfulness. Ballard's results are congruent with the results of the present study as some of the research participants complained of failing to remember the messages they received during the health education that they perceived as being too long.

Sub-category 2.2.2: Poor adherence to treatment

Poor adherence to either ART or TB treatment was mostly cited as one of the major challenges for most of the children. The parents sometimes felt that the medication was too much for the child and decided to skip some when they were supposed to give the medication to their children. Their words were captured exactly as stated below:

"This is difficult at times since the tablets are too many. I will not lie to you, I use to give my child breaks. The tablets were too big for the child to be swallowed. But I thank God that he was cured for the TB, though I had to receive a series of counselling sessions" Participant 2, 7, 9, 11 & 12.

"Giving both TB and HIV medication to your child is not a joke. I used to forget this and be reminded by the child herself" Participant 1, 5, 6, & 8.

The results of the study have cited high pill burden and forgetfulness as some of the barriers to adherence to the TB and ART treatment. These are similar to the findings of a study that was conducted in Canada which identified that the large number of medication doses, in addition to multiple recent medication changes, were likely contributing to our patient's anxiety, confusion and subsequent lack of adherence (Farrell, Merkley & Ingar

2013:265 & Sheppard, Weber, Casaletto, Avci, Woods, Grant, Atkinson, Ellis, McCutchan, Marcotte & Marquie-Beck 2016:600). Other factors that literature have identified as barriers to adherence were distance to the health facility, long patient waiting time, patients' attitudes and poor health education (Sheppard et al 2013:607 & Schwitters, Lederer, Zilversmit, Gudo, Ramiro, Cumba, Mahagaja & Jobarteh 2015:109).

4.6 DISCUSSION OF THE RESULTS

Theme 1: Nutritional situation at home

The study revealed that the caregivers understood the importance of good nutrition during TB treatment. They acknowledged that the nutrition provided to the child before and during the course of the treatment was not adequate. This was noted when most of the caregivers complained of un-balanced diet given to children, some children were mixed-fed and others complaint of loss of social support due to death of a breadwinner.

Poor Nutrition and HIV/AIDS amongst the children were perceived as major causes for the development of TB, hence poor TB outcomes. A social determinant's framework also highlights how lack of hope for the future, driven by poverty, might also foster high rates of treatment default that undermine TB control and other poor TB outcomes. Also the close relationship between HIV and TB in many settings, notably sub-Saharan Africa, the key structural and social determinants of HIV infection also act as indirect determinants of TB risk, especially amongst children less than 15 years old (Hargreaves, Boccia, Evans, Adato, Petticrewand & Porter 2011:3).

All the caregivers revealed that their children were exposed to poor nutritional situations at their homes. Some families had more children to feed than the ones they could afford, yet others claimed that they lacked food due to unemployment. Therefore, after considering all the perceptions of the caregivers with regards to the nutrition situation at home, it is indicated that malnutrition was the contributing cause for TB amongst the children.

Theme 2: Nutritional support from the health care facility

The results of the study indicated that most of the children had nutritional support from the health care facility. Younger children were given plumpy nut supplies and the older

children were given food by prescription. Challenges that were faced by the caregivers were the inconsistent nutritional support, sharing of the food therapy with non-deserving family members, too long health education and poor adherence to ATTs.

A study conducted in Zambia further reports that food was not always dispensed from the pharmacy as per guidelines due to space, existing burden on pharmacy staff with distributing medication, poor services integration and lack of forecasting and stock management (Catholic Relief Services 2012:8).

4.7 CONCLUSION

This chapter presented and discussed the results of the study according to the main objective of the qualitative phase of the study. These results were discussed according to exiting literature and the context of which the study took place. The next chapter provides a general discussion, merging of both the quantitative and qualitative results and then makes recommendations based on the results of the two study phases.

CHAPTER 5

SUMMARIES, INTEGRATION OF RESULTS AND CONCLUSIONS

5.1 INTRODUCTION

The first objective of the chapter is to summarise and integrate the results for first and phase two of the study through making comparison and contrast between the two. The second objective is to provide the study conclusions, limitations and recommendations. The purpose of the study was to examine the association between malnutrition and diagnosed drug susceptible TB amongst children aged zero to 15 years old in Swaziland.

5.2 RESEARCH DESIGN AND METHOD

Selected variables of children zero to 15 years old diagnosed with drug susceptible TB were collected through a retrospective cohort design for phase one of the study. In phase two of the study individual semi-structured interviews were conducted with purposively selected caregivers who were taking care of the children at least six months before the child got diagnosed with TB, during the TB treatment course and six months after completion of the treatment. A mixed method approach was followed.

Data for the quantitative phase were analysed using Stata software version 14 and data for phase two were analysed following qualitative content analysis. The findings for both phases of research indicated that malnutrition is strongly associated with diagnosed drug susceptible TB amongst children zero to 15 years of age.

Finally, selected variables that included anthropometric measurements and clinical factors for the children were used in determining the association of malnutrition and TB disease outcomes in children aged zero to 15 years old. This has helped in providing an evidence base for more comprehensive integration between nutrition programs, TB treatment programs and HIV programs. Furthermore, the results of the study contributed to the growing body of knowledge about the association between malnutrition and diagnosed drug susceptible TB among children aged zero to 15 years old. The findings will provide a basis for recommendations towards the formulation of appropriate policies and guidelines aimed at addressing the issues of malnutrition on TB and TB/HIV co-

infection clients, especially children under the age of 15 years, who are most commonly affected by malnutrition in Swaziland.

5.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS FOR THE FIRST QUANTITATIVE PHASE

The objectives of phase one of the study were to describe the clinical and demographic characteristics of malnutrition amongst children zero to 15 years of age with drug susceptible TB and to examine the factors associated with malnutrition and drug susceptible TB diagnosis amongst them. The research findings were categorized according to each of the objective.

5.3.1 Clinical and demographic characteristics of the children

A total of 306 children's EMRs were sampled for the quantitative phase. Sex representation was 49.3% of the EMRs for males and 50.7% were for females. The ages were divided in to four categories; zero to six months old, seven to 59 months old, five to ten years old and 11 to 15 years old. The graph below illustrates the age categories of the children whose EMRs were sampled.

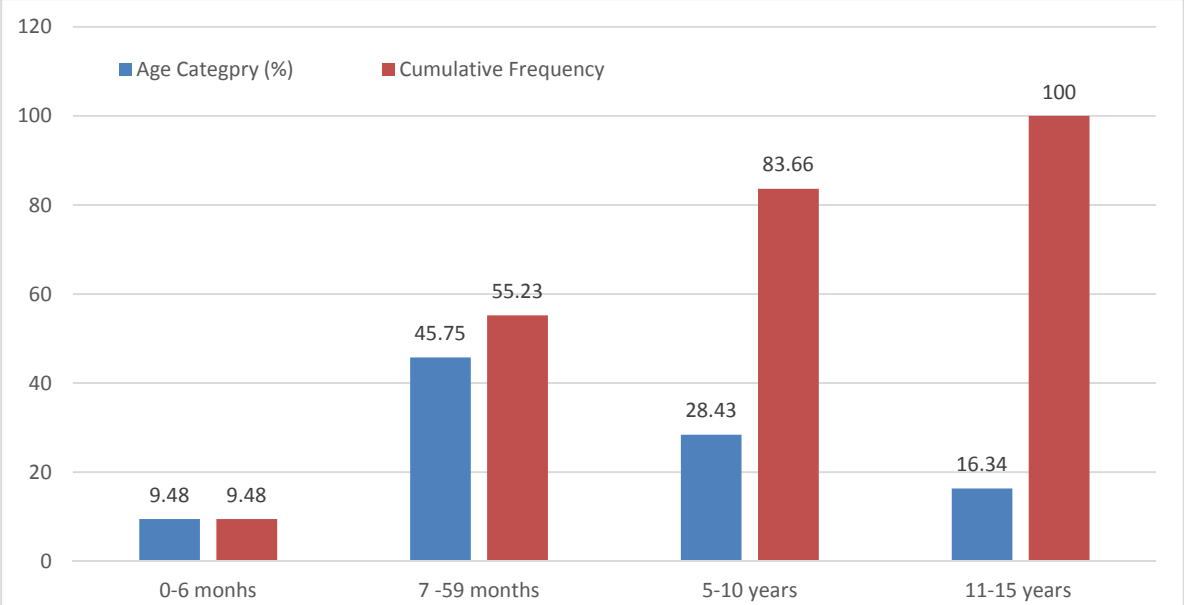

Fig. 5.1 Age categories representation

Figure 5.1 Age categories representation

The category of the EMRs of children aged zero to six months were 9.48% of the total, the six months to 59 months category had 45.75% of the total, the five to ten years old had 28.43% of the total and the last category of 11 to 15 years old had 16.34%. Each of these age categories were screened for malnutrition using weight for height Z-score (wasting); age for height Z-score (stunting) and the weight Z-score to screen for underweight before the initiation of TB treatment.

5.3.2 Factors associated with malnutrition and drug susceptible TB

The researcher considered a number of variables to measure the association between malnutrition and diagnosed drug susceptible TB. The variables that were extracted were the haemoglobulin (HB), Middle Upper Arm Circumference (MUAC), HIV status, ART status, ART regimen, age and type of TB. The study found children in the age less than six months to have moderate and severe malnutrition, and that was strongly associated with poor TB outcomes.

5.4 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS FOR THE QUALITATIVE PHASE

The objective of the qualitative phase of the study was to explore and describe the perceptions of the children's caregivers with regard to paediatric nutrition during TB treatment. The findings of the qualitative phase are summarized below:

5.4.1 The demographic characteristics of the study participants

A total of 12 caregivers of the children whose EMRs were selected for data extraction were purposefully selected to be interviewed using semi-structured interviews guides.
The majority, 5/12 (41.7%) of the participants was aged 40 to 49 years, followed by the group aged 30-39 years with 4/12 (33.3%), then 18 to 29 years old at 2/12 (16.7%) and the age group of 50 to 65 years old at 1/12 (8.3%). Only 2/12 (16.7%) were single, 5/12 (41.7%) were married and the other 5/12 (41.7%) were widowed. All participants had received some form of formal education with most of them having attained secondary school qualification, and the minority holding tertiary qualification. Only one of the participants was employed and the rest were unemployed. However, all of the families

had at-least one employed family member. Most of the families had more than three children to feed and only one had one child.

5.4.2 Perceptions of the caregivers with regard to paediatric nutrition

All the caregivers that participated in the study felt that there was a poor nutritional situation in their homes that resulted into poor nutrition, hence the development of TB disease. Other factors that were cited along with the poor nutrition at home were HIV infection and poor ART adherence. The malnutrition was assumed to be caused by a number of factors as listed below:

- Lack of a balanced diet
- Mixed feeding of children less than six months
- Death of biological caregivers
- Unemployment, which contributes to lack of food
- A high number of children than what the family could afford
- Inconsistent supply of plumpy nut packages at health facility
- Inconsistent supply of food by prescription supplies
- Sharing of the food therapy amongst children
- Health education too long
- Poor adherence to the anti-TB therapy

5.5 INTEGRATION OF QUANTITATIVE AND QUALITATIVE OF THE RESULTS

According to Santos, Erdmann, Meirelles, Lanzoni, Cunha and Ross (2017:3) integration in mixed method research occurs when both the quantitative and the qualitative databases are fused and produce information that support each other mutually. In the study, the qualitative findings were able to give rationale for the children to develop TB and have poor TB outcomes. Both the quantitative and the qualitative phases of the study found that moderated to severe malnutrition (wasting and underweight) were the causes of drug susceptible TB amongst the children zero to 15 years old. Other confounding factors were HIV positive status, history of TB treatment and age. Creswell (2013:32) further states that mixed method approach integrates the two forms of data and uses distinct designs that may involve philosophical assumptions and theoretical frameworks. The core assumption of the approach is that the combination of quantitative and

qualitative approaches promotes a more complete understanding of a research problem than either approach alone.

Even though there was no association between geographical area location and the poor TB outcomes in the quantitative phase of the study, the qualitative phase found that most of the caregivers were assuming that their children were malnourished because they were living in rural areas. The standards of living in rural areas were assumed to be the causes for poor nutrition to their children. Other factors that were statistically insignificant in the quantitative phase were the type of TB (pulmonary or extra-pulmonary), administrative region and sex. Those results were congruent to the results of the findings of the qualitative phase as none of the caregivers reported child's sex, administrative region and the type of TB to be the cause for developing TB.

5.6 CONCLUSIONS

The findings of the study call for evidence-based and practical interventions to assist caregivers in complementing the efforts of the clinicians in the fight against malnutrition in children diagnosed with drug susceptible TB. The factors identified to be associated with drug susceptible TB amongst children aged zero to 15 years old were used to recommend quality interventions against TB. Each recommended intervention was made based on an identified problem or challenge; and rationale to each recommendation is presented. The recommendations will be referred to the Swaziland Ministry of Health, Baylor College of Medicine Children's Foundation Swaziland and National TB Program and supervisors in the TB units.

5.7 RECOMMENDATIONS

The UNISA MNUALLL (2016:83) reports that recommendations should include thoughts about future studies that will be conducted in different provinces that problems encountered could be addressed in specific ways, or that the research populations for future research be defined differently.

5.7.1 Recommendation for practice

5.7.1.1 Understanding the general concept of malnutrition in children with TB

The following recommendations are formulated with the view to contribute knowledge at the practical level.

Recommended intervention 1: Swaziland MoH, NTCP, BCMCF-SD management and relevant policy-makers are urged to implement the following organisational and policy measures:

- Design and distribute pamphlets with essential information to include management of malnutrition, TB and HIV.
- Develop curricula that will have lesson plans to educate caregivers on the food therapy for managing malnutrition
- Capacitate nurses and other health care workers to assist parents and caregivers with relevant information related to malnutrition on children diagnosed with TB.
- Incorporate a session in health education in the notational TB guidelines. It should be stated that the health education should not exceed 15 minutes of the caregivers' time to reduce patient waiting time.
- Start support groups for children aged zero to 15 years old diagnosed with TB and their caregivers to enhance adherence to the TB treatment and improve TB outcomes (Paz-Soldán, Alban, Jones & Oberhelman 2013:6).

Rationale: The rationale of the foregoing is to strengthen the health system with regard to the management of malnutrition in children diagnosed with TB and improve involvement of the caregivers in the management their children.

5.7.1.2 Perceptions of the caregivers with regard to malnutrition of children zero to 15 years old diagnosed with drug susceptible TB

Recommended intervention 2: BCMCF-SD Health care workers and other TB health care facilities are urged to implement the following interventions:

- Consider family and community dynamics during health education of the children's caregivers.
- Seek the support of a psychologist, social worker or counsellor to assist caregivers psychologically while rendering support to the child diagnosed with TB.
- Encourage caregivers to disclose TB status of their infected children.
- Arrange debriefing sessions for caregivers every three months and allow them to share experiences and copying strategies.
- Acknowledge individuality among caregivers on the management of malnutrition.

Rationale: To enhance the management of malnutrition in children diagnosed with TB amongst their caregivers and improve the outcomes of TB in children.

5.7.2.1 Recommendations for further research

Recommended intervention 3: Further research studies that are recommended are listed below:

- Evaluating the understanding of health care workers in the management of malnourished children diagnosed with drug susceptible TB.
- Evaluation of the psycho-social support rendered to malnourished children diagnosed with TB.
- Evaluating the national TB guidelines with regard to the management TB amongst children aged zero to 15 years old.

Rationale: To further evaluate the understanding of the health care workers and the psycho-social support rendered with regard to the management of malnutrition in children aged zero to 15 years old diagnosed with drug susceptible TB. The evaluation of national TB guideline can be conducted to inform policy makers on possible avenues to improve the management of TB in children.

5.8 CONTRIBUTIONS OF THE STUDY

The study examined the association of malnutrition and TB disease outcomes in children zero to 15 years of age in Swaziland. This has provided evidence-based information for

more comprehensive integration between nutrition programs, TB treatment programs and HIV programs. Furthermore, the results of the study has contributed to the growing body of knowledge about the association between malnutrition and diagnosed drug susceptible TB among children aged zero to 15 years old. The findings assisted in the formulation of appropriate recommendations for policies and guidelines aimed at addressing the issues of malnutrition on TB and TB/HIV co-infected children.

In addition, the findings guided and improved the quality of care to all TB clients, especially children under the age of 15 years, who are most commonly affected by malnutrition in Swaziland.

The study has contributed at the theoretical level by identifying the factors that are associated with poor TB outcomes in children less than 15 years old.

5.9 LIMITATIONS OF THE STUDY

The study was limited to EMRs of children aged zero to 15 years' old that were treated for TB disease at BCMCF-SD at Mbabane from the 1st January 2008 to 31st July 2016. Retrospective data has potential of selection biasness and it is difficult to make comparison between the exposed and the non-exposed (Creswell 2014:25). Therefore, the researcher conducted random sampling and validated the data using a paper based TB register. Semi-structured interviews were conducted to complement the retrospective data with the qualitative results of phase two. The study enrolled only the caregivers of the children zero to 15 years' old, whose EMRs were selected for data extraction. The researcher decided to interview caregivers of children treated in the period of the periods of 1st January 2014 to 31st July 2016, because caregivers of children treated more than two years ago would have forgotten critical information that was needed during the interview.

5.10 COMMUNICATING THE FINDINGS

Communicating the findings involves the development and distribution or giving out of a research report to appropriate audiences (Brink, Van der Walt & Van Rensburg 2014:50). The researcher will communicate the results of the study to the Swaziland Ministry of Health, National TB Control Program and Baylor College of Medicine Children's

Foundation. The researcher will publish a peer reviewed journal article for the benefit of countries extrapolation beyond Swaziland.

5.11 CONCLUDING REMARKS

The findings of the study have provided evidence-based information and practical guidelines to assist caregivers and health care workers in the management of malnourished children diagnosed with drug susceptible TB. The gaps identified on the management of the malnourished children diagnosed with TB and the factors associated with TB were used to formulate the recommendations that have the potential to enhance the management of malnutrition amongst children diagnosed with TB. Each of the recommendations was formulated based on an identified problem or challenge; and rationale for the guidelines was presented. The recommendations will be referred to the Swaziland Ministry of Health, National TB Control Program and Baylor College of Medicine Children's Foundation Swaziland.

The findings of the study will be disseminated through the research report, which will be sent to the Swaziland Scientific and Ethics Committee, BCMCF IRBs (Both in Swaziland and in the USA) and the National TB Control Program. Also dissemination of the findings will be done through publication of the research in the Southern African Journal of Infectious Diseases and presentation at relevant forums such as workshops, conferences, congresses and updates.

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ANNEXURES

ANNEXURE A: ETHICAL CLEARANCE CERTIFICATE FROM THE UNIVERSITY OF SOUTH AFRICA

UNISA university of south africa

RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES

REC-012714-039 (NHERC)

15 February 2017

HSHDC/611/2017
Mr BS Tsabedze
Student: 5446-392-0

Supervisor: Dr DSK Habedi
Qualification: D Litt et Phil
Joint Supervisor: -

Dear Mr BS Tsabedze

Decision: Ethics Approval

Name: Mr BS Tsabedze

Proposal: Association between malnutrition and diagnosed drug susceptible tuberculosis amongst children aged zero to fifteen years old in Swaziland.

Qualification: MPCHS94

Thank you for the application for research ethics approval from the Research Ethics Committee: Department of Health Studies, for the above mentioned research. Final approval is granted for the duration of the research period as indicated in your application.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on 15 February 2017.

The proposed research may now commence with the proviso that:

1) *The researcher/s will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.*

2) *Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study, as well as changes in the methodology, should be communicated in writing to the Research Ethics Review Committee, Department of Health Studies. An amended application could be requested if there are substantial changes from the existing proposal, especially if those changes affect any of the study-related risks for the research participants.*

Open Rubric

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392 UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsimile: +27 12 429 4150
www.unisa.ac.za

3) *The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study.*

4) *[Stipulate any reporting requirements if applicable].*

Note:
The reference numbers [top middle and right corner of this communiqué] should be clearly indicated on all forms of communication [e.g. Webmail, E-mail messages, letters] with the intended research participants, as well as with the Research Ethics Committee: Department of Health Studies.

Kind regards,

Prof L Roets
CHAIRPERSON
roetsl@unisa.ac.za

Prof MM Moleki
ACADEMIC CHAIRPERSON
molekmm@unisa.ac.za

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392 UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsimile: +27 12 429 4150
www.unisa.ac.za

ANNEXURE B: LETTER REQUESTING FOR PERMISSION TO CONDUCT THE STUDY AT BCMCF-SD

BOX 3614
MANZINI
M200
SWAZILAND

30 May 2016

THE EXECUTIVE DIRECTOR
BCMCF-SD
BOX 110
MBABANE

DEAR MADAM

APPLICATION TO CONDUCT A STUDY ABOUT THE ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND

I, Bhekisisa Senzo Tsabedze, am currently enrolled for a degree of Masters' in Public Health in the Department of Health Studies at the University of South Africa (UNISA) under supervision of Dr DSK Habedi and Mr. MT Mamahlodi. I hereby request to conduct a research study about the association between malnutrition and diagnosed drug susceptible tuberculosis amongst children aged zero to fifteen years old in Swaziland.

The purpose of the study was to examine the association between malnutrition and diagnosed drug susceptible TB amongst children aged zero to 15 years old. The study will involve the electronic medical records (EMRs) for children treated for tuberculosis (TB) while aged zero to fifteen years old and the caregivers of those children, whose EMRs will be reviewed. For missing EMRs data will be confirmed with the TB register.
I will conduct data extraction from the EMRs and the TB register and then return the TB register to the TB unit.

The children's caregivers will be invited to voluntary participate in this research study. I promise to adhere to all scientifically, legally and morally acceptable ethical conduct. I will make sure that the risk of participating in the semi-structured interview remains minimum or absolutely eliminated by following the appropriate research ethics. Confidentiality and anonymity will be maintained at all levels of the study. Ethical approval from the University of South Africa, Swaziland Scientific & Ethics Committee (SSEC) and BCMCF-SD IRB will be obtained prior to data collection.

I further, promise that I will inform the participants about the extent of utilization of the data derived from the research. Any caregiver willing to and volunteering to participate in the research project will be enrolled if meeting the eligibility criteria. Please be ensured of my utmost integrity in this research project, which will not be invasive, having no interaction with minors and there will be no medication of any kind given to the study participants.

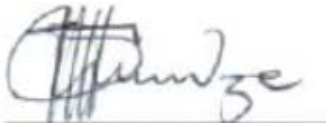
I shall conduct the study strictly in accordance with the approved proposal requirements of the ethics policy of UNISA, SSEC and Baylor College of Medicine Children's Foundation Swaziland Institutional Review Board BCMCF-SD's IRB. I hope my application will be favourable considered.

My contact details are as follow;

Cell: +26876452248 Work: 0026824096025 Home: 0026825059475

Emails: bhekisisatsabedze@ymail.com / btsabedze@baylorswazialnd.org.sz

Yours faithfully



Mr. Bhekisisa Senzo Tsabedze

ANNEXURE C: BAYLOR COLLEGE OF MEDICINE CHILDREN'S FOUNDATION-SWAZILAND INSTITUTIONAL REVIEW BOARD'S APPROVAL.

Baylor College of Medicine
Children's Foundation – Swaziland
Corner of Somhlolo and Sigwili Street
Kent Rock, Mbabane, Swaziland
P.O. Box 110 Mbabane. Swaziland
Phone: (+268) 4096000/4040133
Fax: (+268) 4040214

From: The Chairperson (Dr. Sarah Perry)
Baylor College of Medicine Children's Foundation-Swaziland (BCMCF-SD)
Institutional Review Board (IRB)
P.O. Box 110
Mbabane

To: Bhekisisa Senzo Tsabedze
PO Box 3614
Manzini

Date: May 19, 2017

Association between malnutrition and diagnosed drug susceptible tuberculosis amongst children aged zero to fifteen years old in Swaziland.

After review of the above-mentioned protocol, the institutional review board for Baylor College of Medicine Children's Foundation-Swaziland (BCMCF-SD IRB) approves the study protocol. The approval period is one year from the time the Swaziland Scientific and Ethics Committee gives its approval and work may not continue after the approval period without additional BCMCF-SD IRB review and approval for continuation.

Please note that only BCMCF-SD IRB approved protocol, informed consent forms, instructions and study tools may be submitted for further IRB review and approval. Any alternations to the study docket before submitting to the next level IRB should be communicated to BCMCF-SD IRB for re-approval. Otherwise changes effected by next level IRBs do not need any review and approval by the BCMCF-SD IRB.

BCM-SD IRB is registered with the United States Office for Human Research Protections and is operating under the IORG #: 0006978.

Yours Sincerely,

Dr. Sarah Hope Perry (MD MPH)
Director of Research
Baylor College of Medicine Children's Foundation-Swaziland

ANNEXURE D: LETTER REQUESTING FOR PERMISSION FROM SWAZILAND SCIENTIFIC & ETHICS COMMITTEE

BOX 3614
MANZINI
M200
SWAZILAND

30 May 2016

THE CHAIR PERSON
Swaziland Scientific & Ethics Committee
BOX 32
MBABANE

DEAR MADAM

APPLICATION TO CONDUCT A STUDY ABOUT THE ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND

I, Bhekisisa Senzo Tsabedze, am currently enrolled for a degree of Masters' in Public Health in the Department of Health Studies at the University of South Africa (UNISA) under supervision of Dr DSK Habedi and Mr MT Mamahlodi. I hereby request to conduct a research study about the association between malnutrition and diagnosed drug susceptible tuberculosis amongst children aged zero to fifteen years old in Swaziland.

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I will conduct data extraction from the EMRs and the TB register and then return the TB register to the TB unit.

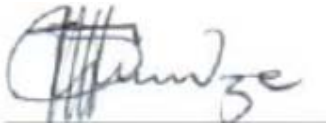
The children's caregivers will be invited to voluntary participate in this research study. I promise to adhere to all scientifically, legally and morally acceptable ethical conduct. I will make sure that the risk of participating in the semi-structured interview remains minimum or absolutely eliminated by following the appropriate research ethics. Confidentiality and anonymity will be maintained at all levels of the study. Ethical approval from the University of South Africa, Swaziland Scientific and Ethics Committee (SSEC) and Baylor College of Medicine Children's Foundation Swaziland (BCMCF-SD) Institutional Review Board (IRB) will be obtained prior to data collection.

I further, promise that I will inform the participants about the extent of utilization of the data derived from the research. Any caregiver willing to and volunteering to participate in the research project will be enrolled if meeting the eligibility criteria. Please be ensured of my utmost integrity in this research project, which will not be invasive, having no interaction with minors and there will be no medication of any kind given to the study participants.

I shall conduct the study in strict accordance with the approved proposal requirements of the ethics policy of UNISA, SSEC, BRAIN and BCMCF-SD's IRB. I hope my application will be favourable considered.
My contact details are as follow;

Cell: +26876452248 Work: 0026824096025 Home: 0026825059475
Emails: bhekisisatsabedze@ymail.com / btsabedze@baylorswazialnd.org.sz

Yours faithfully



Bhekisisa Senzo Tsabedze

ANNEXURE E: SWAZILAND SCIENTIFIC & ETHICS COMMITTEE CLEARENCE CERTIFICATE

Research Protocol clearance certificate

Type of review	Expedited	X		Full Board			
Name of Organization	**STUDENT**						
Title of study	**ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND**						
Protocol version	**1.0**						
Nature of protocol	New			Amendment	x		
List of study sites	**BAYLOR COLLEGE OF MEDICINE CHILDRENS FOUNDATION, MBABANE**						
Name of Principal Investigator	**BHEKISISA TSABEDZE**						
Names of Co- Investigators	**DR ANNA MANDALAKAS**						
Names of steering committee members in the case of clinical trials	**N/A**						
Names of Data and Safety Committee members in the case of clinical trials	**N/A**						
Level of risk (Tick appropriate box)	Minimal			High			
	X						
Clearance status (Tick appropriate box)	Approved	**X**		Disapproved			
Clearance validity period	Start date	**06/06/2017**	End date	**06/06/2018**			
Signature of Chairperson							
Date of signing	**08/06/2017**						
Secretariat Contact Details	Name of contact officers	**Ms Simangele Masilela**					
	Email address	kaluamasi@gmail.com					
	Telephone no.	**(00268) 24040865/24044905**					

MINISTRY OF HEALTH
19 SEP 2017
HEALTH RESEARCH REVIEW BOARD
SWAZILAND

Page 1 of 2

Approval Conditions

1	Implementation of approved version of protocol	✓				
2	Reporting of adverse events within 5 days of occurrence	✓				
3	Submission of progress reporting for multi-year studies	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
		N/A	N/A	N/A	N/A	N/A
4	Submission of end of project report (Hard copy)	✓				
5	Submission of end of project report (Soft copy)	✓				
6	Submission of data sets	✓				

List of reviewed documents

Ref.	Documents	Reviewed documents (tick appropriate box)
1	Completed application form	✓
2	Cover letter	✓
3	Evidence of administrative permission to conduct the research by involved institutions/sites (where applicable)	✓
4	Detailed current resume or curriculum vitae of Principal Investigator/s including Principal investigators declaration	✓
5	Summary resume or biography for other investigator(s)	✓
6	Evidence of approval/rejection by other Ethics Committees, including comments and requested alterations to the protocol, where appropriate.	
7	Research protocol (see outline in Annex 1)	✓
8	Questionnaires and interview guides (with back-translated versions where applicable)	✓
9	Case report forms (CRFs), abstraction forms and other data collection tools	✓
10	Participant/subjects Information Statement(s) (where applicable)	✓
11	Informed consent form(s) including photographic and electronic media consent statements.	
12	Advertisements relevant to the study (where applicable)	
13	Source of funding and detailed budget breakdown including material and incentives to participants if applicable	
14	Notification form for adverse effects/events.	
15	Proof of payment	✓
16	Proof of insurance cover for research subjects in clinical trials or where applicable	
17	Any other special requirements should be stated, if applicable	None

Participant's (Caregiver) Unique ID……

ANNEXURE F: INFORMED CONSENT FORM (ENGLISH)

Statement concerning participation in a Research Project:

TITLE: ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND.

I have read the information and heard aims and objectives of the proposed study and was provided the opportunity to ask questions and given adequate time to rethink about the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressured to participate in any way.

I understand that participation in the study is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no negative influence on me and the family as I access health care services at BCMCF-SD or any other health care institution in the country. I know that the study has been approved by the Swaziland Ministry of Health, Baylor clinic and the University of South Africa. I am fully aware that the results of the study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed. Therefore, I hereby give consent to participate in the study.

. . . .

Inombolo yalongenele lucwaningo ID……

ANNEXURE G: INFORMED CONSENT FORM (SISWATI)

Statement concerning participation in a Research Project:

SIHLOKO: BUDLELWANE EMKHATSINI WESIFO SEDLALA NESIFO SESIFUBA SENGATI KUBANTFWANA LABANGEPHANSI KWEMINYAKA LELISHUMI NESIHLANU ESWATINI.

Nginesiciniseko kutsi ngifundzile lomniningwano walolucwaningo, ngiphindze ngaptfola incazelo leyenetisako. Nginiketiwe litfuba lekubuta imibuto nekutsi ngicabangisise ngekungenela loluncwaningo. Ngiyacaceleka ngenjongo nemigomo yalolucwaningo, futsi ngiyacondza kutsi angikacindzeteleki kutsi ngilingenele.

Ngiyacondza kutsi angikaphocelelwa kungenela lolucwaningo, ngilungenela ngekutsandza kwami, futsi uma sengifuna kuphuma kulolucwaningo nginga phuma noma ngabe ngusiphi sithatsi ngaphandle kwekutsi ngibeke tizatfu. Uvele nje watise umcwaningi kutsi awusatsandzi kuchubeka nalolucwaningo. Nangabe kukhona imininingwano losinike yona sitoyilahla. Loyo lompumile kulolucwaningo utochubeka alashwe noma ngabe ngumuphi umtfilampilo lapha kangwane, kufaka ekhatsi iBaylor (BCMCF-SD) nelusito latolutfola lutochubeka lube sezingeni lelisetulu.

Ngiyati kutsi lolucwaningo luvunyelwe litiko letempilo Eswatini, yiBaylor, Kanye nenyuvesi yaseningizimu. Ngiyati kutsi imiphumela yalolucwaningo itewusenjetiswa kutsi kulwashe sifo sendlala Kanye nesifo sesifuba sengati ngelucophelo lelisetulu lwebucwephesha. Ngako-ke ngiyavuma kungenela lolucwaningo uma imininingwano yami nemntfwana itewugcinwa iyimfihlo.

. . . . .	. . . . .
Libito lalongenele lucwaningo	Sayina/ Sifakazelo
. . . . .	. . . . .
Indzawo	Lusuku

ANNEXURE H: INFORMATION SHEET (ENGLISH)

Participant's Unique ID……

TITLE: ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND.

Why does the researcher do the study?

The study is a partial fulfillment for the requirement for the Masters' of Arts in Public Health (MPH) Degree for the researcher. The purpose of the study is to examine the association between malnutrition and diagnosed drug susceptible tuberculosis (TB) amongst children aged zero to fifteen years old in Swaziland. Thus, the results will be used to improve the quality of care given to children under fifteen years old diagnosed with TB disease.

Therefore, the researcher thinks that you might be a suitable candidate to participate in the study since your child was less than fifteen years old when undergoing treatment for TB disease and you provided care to him/her before, during and after that period.

What happens if one wants to be part of the study?

If you want to participate in the study, the researcher will ask a series of questions regarding the child and household's eating habits before starting the TB treatment, during and after completion of the TB treatment. The researcher will keep all the information collected in a secure and separate file.

What things can happen to you?

The researcher will ask to meet you and your child in a private room to answer certain questions about the child. Even if the child is not present the researcher can carry on with the interviews. This can take forty-five minutes of your time and it can also bring certain emotional responses especial for parents that lost their children. If such happens the researcher will stop the session and concentrate on psychosocial support (PSS) and counseling and can offer referral to a qualified social worker for further counselling. You may ask that the interview be stopped at any time. If you decide to stop the interview, there will be no impact on you or on your child's clinical care.

Is there any good thing if one participates in the study?

You will not get money or other direct benefits. If you have come only for the study outside normal clinical visits, the researcher will pay for your round trip transport fee.

The results will be used to raise awareness of the nutritional needs of children under fifteen years old diagnosed with TB disease and improve quality of care given to these age group.

Who will know about information collected from the study?

All the information that will be shared with the researcher will be kept secured and privatized. The name of the participant will not link with the information provided. Each participant will be given a unique code, which will be known by the researcher.

When the researcher has gathered all the information together will remove all the unique codes and the conclusions will be shared with the BCMCF-COE, UNISA, Swaziland Ministry of Health and the National TB Control Program (NTCP), so that everyone can learn from the findings of the study.

What happens if one wants to leave the study before the end of the interviews?

Being a participant in the study is completely voluntary. If one decides to stop participation, one simply should to inform the researcher that one no longer wishes to participate. The collected information from that individual will be discarded.

The individual and family will continue to be BCMCF-COE clients and will continue to receive quality clinical care.

For any questions or concerns, please contact:

The researcher: Bhekisisa S. Tsabedze at +268 7645 2248.

Inombolo yalongenele lucwaningo: ……

ANNEXURE I: INFORMATION SHEET (SISWATI)

SIHLOKO: BUDLELWANE EMKHATSINI WESIFO SEDLALA NESIFO SESIFUBA SENGATI KUBANTFWANA LABANGEPHANSI KWEMINYAKA LELISHUMI NESIHLANU ESWATINI.

Umcwaningi ulwentelani lolucwaningo?

Lolucwaningo luluhlelo loludzingekile kutsi uncwaningi alwente kuze atocedzela tifundvo takhe tenmfundvo lephakeme enyuvesi yaseNingizimu Africa (University of South Africa). Injongo yalolucwaningo kutsi sihlole budlelwane emkhatsini wesifo sedlala nesifo sesifuba sengati kubantfwana labangephansi kweminyaka lelishumi nesihlanu eswatini. Imiphumela yalolucwaningo itewusentjetiswa kutfutfukisa lizinga lekunakekelwa kwebantfwana labangephansi kweminyaka lelishumi nesihlanu lesebagagulwe kutsi banaso sifo sendlala nesifuba sengati.

Ngako-ke lomcwaningi ucabanga kutsi ungaba ngumuntfu lokahle kutsi ungalungenela lolucwaningo, kulandzela kutsi uke wanankekela unfwana lobekalashelwa sifo sesifuba sengati akuleminyaka lengaphansi kwalelishumi nesihlanu.

Kungentekani nangabe ufuna kungenela lolucwaningo?

Uma ufuna kungenela lolucwaningo, ucwaningi utokubuta luhla lwemibuto lephatselene nempilo yemtfwana, nendlela yekudla ekhaya asengakacali kgagulwa kutsi unalesifo, noma sekalashwa, nangesikhatsiu sekacedzile kulashwa. Lomcwaningi utogcina lonkhe lwati lotomnika lona luvikelekile futsi luyimfihlo efayeleni lelikhiyelwe ekhabetheni, nasedlini lekhiywako.

Yini tintfo lelingenteka kuwe?

Umcwamingi Kanye nemsiti wakhe batokucela kutsi bakubonele endzaweni lapho kute khona bantfu labanye nalapho kungenamsindvo khona (Kungaba sendlini) lapho atotsandza khona kutsi umatise kabanti ngempilo yemntfwana. Loku kungatsatsa imizuzu lengemashumi lamatsatfu kuya kulengemashumi lamane nesihlanu, futsi kungenteka

kuvuse tilondza tsite ikakhulu kubatali labashonelwa bantfwana babo. Uma kungenteka lokunjalo umcwaningi utolimisa lolucwaningo abese umniketa teluleko letifanele, angakwendlulisela nakubeluleki labaceceshiwe. Nawe unalo lilungelo lekutsi ungacela kutsi lolucwaningo lumiswe nome ngakusiphi sikhatsi. Uma ukhetsa kutsi ungasalungeneli lolucwaningo leso sincumo ngeke sitsikabete kunakekelwa kwentfwa wakho ka nawe nome ngabe ngumuphi umtfola mpilo lapha kangwane.

Kukhona yini buhle bekungenela lolucwaningo?

Kute inzuzo leyimali noma sipho losita kuwe ngco, kepha nangabe uta ngetikhatsi letingacondzani nemalanga ekuta kwakho etfolampilo sitokunika imali lewute ngayo neyekujika.

Imiphumela yalolucwaningo itewusentjetiswa kutfutfukisa lizinga lekunakekelwa kwebantfwana labangephansi kweminyaka lelishumi nesihlanu lesebagagulwe kutsi banaso sifo sendlala nesifuba sengati.

Ngubani lotokwati ngalemininingwano letfolakale kulolucwaningo?

Yonkhe lemininingwano leniketwe umcwaningi nemsiti wakhe, lomcwaningi utogcina lonkhe lwati lotomnika lona luvikelekile futsi luyimfihlo efayeleni lelikhiyelwe ekhabetheni, nasedlini lekhiywako. Wonkhe longenela lolucwaningo utoniketwa inombolo yelucwaningo leyehlukile letokwatiwa ngucwaningi nemsiti wakhe kuphela. Ligama lalongenele lucwaningo ange lona luhlanganiswe nalenombo.

Uma ucwaningi sekacedze bonkhe labangenele lolucwaningo, lenombolo yekucwaningo itewususwa, bese letiphetfo nemiphumela yalolucwaningo siyetfula esibhedlela sebantfwana eBaylor (BCMCF-SD), enyuvesi yaseningizimu Africa (UNISA), etiko letemphilo eswatini Kanye nasephikweni lelibuke kulashwa kwe sifo sesifuba sengati kuze sonkhe sitofundza kulemiphumela.

Kwentekani uma sewufuma kuphuma kulolucwaningo lungakapheli?

Kute lophocekelile kutsi angenele lolucwaningo. Unelilungelo kutsi ungakhetsa kuluyekela nama ngusiphi sikhatsi lapho uva ungasatsandzi ngaso. Uvele nje watise

umcwaningi kutsi awusatsandzi kuchubeka nalolucwaningo. Nangabe kukhona imininingwano losinike yona sitoyilahla.

Loyo lompumile kulolucwaningo utochubeka alashwe noma ngabe ngumuphi umtfilampilo lapha kangwane, nelusito latolutfola lutochubeka lube sezingeni lelisetulu.

Uma unembuto ungashayela ucwaningi:

Bhekisisa S. Tsabedze at +268 7645 2248.

ANNEXURE J: SEMI-STUCTURED INTERVIEW GUIDE

INTERVIEW PROTOCOL PROJECT: ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND.

1.1 Time of Interview: _____

1.2 Date: _____

1.3 Place: _____

1.4 Interviewer: _____

1.5 Interviewee: _____

1.6 Position of interviewee: _____

2.0 DEMOGRAPHIC DATA OF INTERVIEWEE:

2.1 Caregiver Gender M [ ] F [ ]

2.2 Caregiver Age [ ] years

2.3 Place of residence: rural [ ] semi-urban [ ] urban [ ]

Brief description of the study

The purpose of the study is to examine the association between malnutrition and diagnosed drug susceptible tuberculosis amongst children aged zero to fifteen years old in Swaziland. Thus, the results will be used to improve the quality of care given children aged zero to 15 years' old diagnosed drug susceptible TB. The researcher thinks that you might be a suitable candidate to participate in the study since your child was less than fifteen years old when undergoing treatment for TB disease and you provided care to him/her before, during and after that period.

4.0 GUIDING QUESTIONS

4.1 What role do you have in taking care of the child?

4.2 Please tell us more, on how was the nutrition of the child at six months before starting TB treatment: during the TB treatment and at least six months post completion of the TB treatment.

4.3 What has been the impact of the family in the nutrition of the child?

4.4 What larger ramifications, if any exist from the nutrition of the child?

Probe on the following:

- Who was responsible for providing food for the child? What was the source of income for the person that was responsible for providing food?
- According to your experience was the food enough for the child? Explain Briefly.
- How often the child did have a balance diet? Please state some of the food she/he use to eat as a balanced diet.
- During the course of TB treatment what kind of nutritional support did you receive and where did to get that support? If it was for the health facility, was it consistent? Please explain.
- What were you doing to make sure that the food given to the child was not shared with other children in the family, so that it could last the entire prescribed period and benefit the sick child?
- After the completion of TB treatment how was the nutritional support?

4.5 What other information would you love to share about the child nutrition?

- What do you think can be done better to ensure that the children on TB treatment can get appropriate nutrition support?

5.0 Thank for participating in the study.

5.1 Once again I want to assure you that confidentiality and anonymity will be maintained throughout this research project. For further clarification do not hesitate to contact the researcher in the following contacts;

Cell: +26876452248 Work: 0026824096025 Home: 0026825059475
Emails: bhekisisatsabedze@ymail.com / btsabedze@baylorswazialnd.org.sz

ANNEXURE K: INTERVIEW GUDE (SISWATI)

LUHLWA LWEKHULUMO NCOCISWANO: BUDLELWANE EMKHATSINI WESIFO SENDLALA NESIFO SESIFUBA SENGATI LESINGAKAGWAMI EBANTFWANENI KUSUKA EKUTALWENI KUYA EMINYAKENI LELISHUMI NESIHLANU ESWATINI

1.1 Sikhatsi sekucocisana: _____

1.2 Lusuku: _____

1.3 Indzawo: _____

1.4 Libito Umcwaningi: _____

1.5 Libito lalongenele lucwaningo: _____

1.6 Sigaba salongenele liciniso: _____

2.0 IMININGWANO YALONGENELE LUCWANINGO:

2.1 Bulili bemnakekeli M [ ] F [ ]

2.2 Budzala bemnakekeli yiminyaka lengu: [ ] Budzala.

2.3 Indzawo lakuhlala khona umnakekeli: Emakhaya [ ] Dvute nelidolobha [ ] Edolobheni [ ]

Inchazelo lemfisha ngalolucwaningo:

Injongo yaloluncwaningo kutfola siphindze sichaze budlelwane emkhatsini wetinhlobonhlobo tesifo sendlala macondzana nemiphumela yesifo sesifuba sengati ebantfwaneni kusuka ekutalweni kuya eminyakeni lelishumi nesihlanu. Ngako ke, imiphumela yalolucwaningo itewusentjetiswa kukhulisa lizinga lekunakekelwa kwebantfwana labaseminyakeni lengaphansi kwalelishumi nesihlanu ekunakekelweni kwabo esifeni sesifuba sengati. Lomncwaningi ucabanga kutsi ungaba lofanele kulungenela lolucwaningo kulandzela kutsi uke wanakekela umntfwana longephansi kwaleminyaka lelishumi nesihlanu uma alashelwa sifo sesifuba sengati.

4.0 IMIBUTO LECONDZISA INKHULUMO NCOCISWANO:

4.1 Sicela usichazele kabanti kunakekela kwakho lontfwana lobekane sifo sesifuba sengati. Bekuyini umsebenti wakho ekumnakekeleni?

4.2 Sicela usatise kabanti ngesimo sekudla kwalomntfwana etinyangeni letisitfupha ungakati kutsi unesifo sesifuba sengati, uma sekalashelwa lesifo sesifuba sengati, nasetinyangeni letisitfupha acedzile kulashelwa lesifo.

4.3 Kube yini imitselela yesimo sekudla lasemndenini ekudleni kwalomntfwana?

4.4 Yini tinkinga letikhona macondzana nekudla kwemntfwa? Butisisisa ngaloku:

- Ngubani lonakekela umntfwana? Wenta mkhucito muni?
- Bekwenele yini kudla kwemntfwana? Chaza.
- Bekawatfola yini emaseko lamatsatfu? Shano loko ebekudla.
- Asalashelwa i-TB watfola luphi lusito lwekudla? Bekungululoluchubekako yini?
- Bewenta njani kitsi lokudla kudliwe ngulumntfwana kuphela?
- Wachubeka yini walutfolwa lusito emva kwekwelashwa?

4.5 Yini lolunye lwati longatsandza kusatisa lona macondzana nesimo sekudla salomntfwana?

5.0 Siyabonga kungenela lolucwaningo.

5.1 Sitophindze sikunike siciniseko sekutsi lonkhe lolwati losinike lona ngalontfwa lutogcinwa luyimfihlo sisachubeka naloluchwaningo noma sesicedzile. Nakukhona lukutsite lofuna kucaciseleka kuko ungangabati kuchumana nemncwaningi kunati tindlela tekuchumana letilandzelako;

Mahlalekhikhini: +26876452248 Emsebentini: 0026824096025 Ekhaya: 0026825059475

Liposi Lwembane: 1. bhekisisatsabedze@ymail.com

2. ssenz1@gmail.com

ANNEXURE L: LIST OF VARIABLES FOR PHASE ONE OF THE STUDY		
Study Number	**Date Start ATTs**	**Sex**
Date Start ATTs	**Date Start ATTs**	**Date Start ATTs**
Date Start ATTs	**TB site; P/EP**	**GXP results Culture**
CD4 count	**HB**	**HIV Status**
Date End ATTs	**TB Outcome**	**category of outcome**

ANNEXURE M: ADVERSE EVENTS FORM

Study Number	Type of Adverse event (crying, mute, etc)	Immediate intervention	Follow up intervention 1	Follow up intervention 1	Final Outcome

ANNEXURE N: EDITORIAL CERTIFICATE

In Thy Light
Muchiyedza
Leseding la one

Prof. S. Tichapondwa Modesto
DLitt et Phil (UNISA); MA-ESL (UZ); BEd Curr (UNISA); BA-Hons (Lond) DiP.Ed (UZ);
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[+267] 737 60 408
ftds_enquiry@yahoo.com

EDITORIAL CERTIFICATE

ASSOCIATION BETWEEN MALNUTRITION AND DIAGNOSED DRUG SUSCEPTIBLE TUBERCULOSIS AMONGST CHILDREN AGED ZERO TO FIFTEEN YEARS OLD IN SWAZILAND

by

Bhekisisa Senzo Tsabedze

Introduction

This serves to confirm that the above-named document has been edited for language. The dissertation is well-written demonstrating a sound command of language, and correct handling of the discourse of research. The primary editorial focus was on language, and secondarily, technical matters and those of research related rigour.

Specific aspects

1. Where instances of repetition were identified, and considered to add little value, these were expunged.
2. In instances where smooth flow of text was targeted, please find red text for your consideration.
3. The red text in square brackets is a reminder for the candidate to review and reconsider so that the intended meaning is adequately projected.
4. Suggestions have been made of more appropriate words to communicate purpose, and these are pointed by arrow immediately after the word/words used by the writer.
5. Although tense is well varied throughout the treatise, suggestions have been made in-text to enhance the tenses. This has also been applied to concord, that is, subject-verb agreement.
6. The citation of sources, using the Harvard System, was largely adhered to. However, I think there is a comma after the author when citation is bracketed, e.g. (Dlamini, 2016:27). Please check and verify.
7. Earlier in the discussion, I suggest you expand some key ideas for the benefit of the audience. I refer to concepts like ‘susceptible TB’. Say what it means in some detail.

8. There is use of ‘retrospective design’. It is advised that this be expanded so that there is clarity what it exactly entails.

On the whole, the dissertation is well-scripted, and should read more proficiently after the researcher has closely worked on it the last time.

Best wishes.

Prof. S. Tichapondwa Modesto [27-10-2018]